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 1                         - VOLUME 2 -

 2              IN THE UNITED STATES DISTRICT COURT

 3              IN AND FOR THE DISTRICT OF DELAWARE

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    PAR PHARMACEUTICAL, INC.,      :   CIVIL ACTION
 6  PAR STERILE PRODUCTS, LLC,     :
    and ENDO PAR INNOVATION        :
 7  COMPANY,                       :
                    Plaintiffs,    :
 8                                 :
                                   :
 9       vs.                       :
                                   :
10  EAGLE PHARMACEUTICALS INC.,    :
                                   :   NO. 18-823-CFC-JLH
11               Defendant.        :    (Consolidated)
    ---------------------------    :
12  PAR PHARMACEUTICAL, INC.,      :   CIVIL ACTION
    PAR STERILE PRODUCTS, LLC,     :
13  and ENDO PAR INNOVATION        :
    COMPANY, LLC,                  :
14                                 :
                    Plaintiffs,    :
15                                 :
         vs.                       :
16                                 :
    AMNEAL PHARMACEUTICALS OF       :
17  NEW YORK, LLC, et al.,         :
                                   :
18               Defendants.       :   NO. 18-2032-CFC-CJB

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20
                             Wilmington, Delaware
21                           Thursday, July 8, 2021
                             8:40 o'clock, a.m.
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23
     BEFORE:   HONORABLE COLM F. CONNOLLY, Chief Judge
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25                               Valerie J. Gunning
                                 Official Court Reporter
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12                 Company, LLC

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 1                    P R O C E E D I N G S

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 3              (Proceedings commenced in the courtroom,

 4     beginning at 8:40 a.m.)

 5

 6              THE COURT:  All right.  Good morning.  Please be

 7     seated.  All right.  Anything I need to attend to before we

 8     get started?

 9              MS. WACKER:  We're going to start with Dr. Park

10     now.  He's doing noninfringement and then invalidity.  There

11     are a couple of exhibits and slides that Par has objected to

12     on the invalidity section, so I'm not sure, Your Honor, if

13     you want us to go forward.

14              We can do noninfringement and deal with those

15     objections before we move to invalidity or we can deal with

16     it as we get to the slides, whatever you prefer.

17              THE COURT:  Maybe it's cleaner to do it all at

18     once.  Mr. Black, what do you think?

19              MR.   BLACK:  The main issue I'm interested in is

20     testimony on lot 788435, for which there's no support.  We

21     can address it when we get to that slide.

22              THE COURT:  Okay.

23              MR.   BLACK:  I'm not sure if there are any

24     objections I'm actually aware of.

25              MS. WACKER:  I thought there were two.  That
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1   makes my life easier.

2   THE COURT: Did you all look at the issue of the

3   subject matter jurisdiction? I want to make sure. Is it

4   the reformulated version that is the listed drug?

5   MR. BLACK: Mr. Goldberg is going to address

6   jurisdiction under 271(e)(1) and I will address jurisdiction

7   under 271(a) and (b).

8   THE COURT: Okay. Now, are you prepared to talk

9   about this? I mean, you don't think there's an issue with

10 jurisdiction?

11   MS. WACKER: I don't think -- we've analyzed

12 this and we don't think there is an issue based on our

13 assessment as well.

14   THE COURT: Okay. So do you agree that the

15 listed drug is a reformulated version?

16   MS. WACKER: It is.

17   THE COURT: Oh.

18   MS. WACKER: My understanding is that because

19 the reformulated drug was filed under the same NDA, that

20 there was a requirement that Eagle certify the patents that

21 were listed even though we were certifying on the earlier

22 formulation. That's just a factor of the Hatch-Waxman

23 statute that required us to do that.

24   THE COURT: Mr. Goldberg, did your client

25 certify to the FDA that the original Vasopressin read on the

1   two asserted patents in this case?

2   MR. GOLDBERG: No, Your Honor. We listed the

3   patents for the NDA and the NDA covered its current product,

4   and we assert that the patents-in-suit cover the current

5   product.

6   THE COURT: But when you filed the NDA, the

7   product that was at issue when you filed was the original

8   Vasopressin. Is that right?

9   MR. GOLDBERG: The original NDA was for original

10   Vasopressin in 2014.

11   THE COURT: You're saying the same NDA then was

12   revised?

13   MR. GOLDBERG: Exactly.

14   THE COURT: To cover the reformulated

15   Vasostrict?

16   MR. GOLDBERG: Yes. It can be amended and

17   supplemented, and when you do that, you submit your

18   supplement. Some can include listing new patents.

19   THE COURT: And when you supplement the NDA to

20   effectively change the product, I mean, that's what was done

21   here. Right? It changed from the original Vasostrict to

22   the reformulated Vasostrict?

23   MR. GOLDBERG: Yes, in some of the supplements.

24   THE COURT: Do you actually say explicitly to

25   the FDA, we're changing the product, or is it, no, it's the

1   same product, because it's the same NDA number?

2   MR. GOLDBERG: Yes. There are regs that explain

3   the different types of supplements you submit. There are

4   some more major than others. There are regs that govern

5   that.

6   In general, you submit your supplement with the

7   data you would need in order to have that product change.

8   In this case it was the reformulated version and the

9   supplement was submitted. I forget exactly what type of

10   amendment that was, but there was an amendment to the NDA

11   saying we're changing the formulation.

12   I can also add that in terms of jurisdictional

13   issue for 271(e)(2), it really doesn't depend on the RLD.

14   You know, what Eagle identified as the RLD. The statute

15   just says it shall be an act of infringement to submit an

16   application under 505(j), that's an ANDA of the Federal

17   Food, Drug & Cosmetic Act or described in Section 505(b)(2)

18   of such act for a drug claimed in a patent for the use of

19   which is claimed in a patent.

20   So here, Par filed a complaint against Eagle

21   alleging that Eagle infringed the '785 and '209 patent by

22   submitting its ANDA and nothing more is required. The case

23   that's controlling here is Vanda Pharmaceuticals versus

24   Westward and the cite is 887 F.3d. 1117, and I'm looking at

25   the page 1124. And it just says in that case, here, Vanda

 1   in its complaint alleged that Westward infringed '610 the

 2   patent under 35 U.S.C. 271 by filing the ANDA.

 3   The same situation here. Nothing more was

 4   required to establish the District Court's subject matter

 5   jurisdiction pursuant to 28 U.S.C., 1338(a).

 6   I have a copy of the case if Your Honor would

 7   like it as well.

 8   THE COURT: No. You are saying it doesn't

 9   matter, I mean, when during the course of the ANDA the

10   patent was listed in the Orange Book?

11   MR. GOLDBERG: No, it does not.

12   MR. BLACK: As it happens, Your Honor, these

13   patents issued after the formulation change, so the

14   formulation changed and the product was launched and then

15   the patents issued.

16   The patents were listed in the Orange Book. The

17   FDA required Eagle to send us a paragraph 4 certification.

18   They sent it. The filing of the ANDA is an act of

19   infringement. It creates jurisdiction.

20   There's also jurisdiction separately and

21   independently under 271(a) and (b) because we're now at the

22   point where Eagle has said if they get approval, they will

23   launch.

24   So the Court has jurisdiction to decide the

25   declaration of what would constitute infringement. It

1   usually doesn't come up in the ANDA cases because if you

2   have a finding of infringement under 271(e), the statute

3   requires that the FDA convert to tentative approval until

4   the expiration of the patent. That's mandatory relief. But

5   if we fail on that point, on 271(a) and (b), the Court has

6   jurisdiction and will ask for sort of a lesser included

7   offense, if you will, a declaration that if they do certain

8   things that would constitute infringement, like if they make

9   a product in the top end of the range because the evidence

10   is that that will float into the range during the product

11   life.

12   That wouldn't give us an automatic right of

13   injunctive relief, but that's an issue we have to deal with

14   if they actually did launch. But we would be entitled to

15   that declaration. And Your Honor would be discharging the

16   Article III duties to determine the dispute between

17   effectively there was a conflict between the regulations

18   governing patent law and the FDA law.

19   So with my overlapping circles, if the PTO has

20   issued a claim which would be infringed by an FDA approval,

21   3.64, you would have the authority, and I would ask that you

22   issue a declaration, and that would constitute infringement

23   to the extent upward drift would create an infringement

24   during the life of the patent.

25   THE COURT: All right. And just also I think

1   what you are saying also is that the product for the NDA,

2   although it started out as original Vasostrict, it morphed

3   into reformulated Vasostrict.

4   MR. BLACK: Right, Your Honor. Just as you have

5   seen their ANDA -- you file a document with the FDA. It's

6   not a document, it's a gigantic, gigantic filing with many,

7   many pieces to it and it's a living document. Both during

8   the ANDA process they keep changing their specs and

9   reporting to the FDA.

10   At some point along the way the FDA is saying

11   not good enough, not good enough. Your impurity data is not

12   good enough. It's not the same as the original Vasostrict.

13   You need to deal with these issues. And then eventually,

14   maybe they'll get an approval, and then the approval sticks,

15   but they may make changes along the way.

16   They've said, for instance, that after they get

17   approval, they are going to make -- they're going to file a

18   separate approval to get these batches made on a different

19   product line because the line that they've been planning to

20   make it on is being taken up by Covid vaccines and that's

21   going to require separate approvals and who knows what will

22   happen when those batches are actually made. But it's a

23   living document.

24   THE COURT: It's a living document, and I use,

25   in terms of figuring out what the relevant product is, I use

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 1    the product that is most current?
 2              MR. BLACK:  Yes.  The law is clear that you have
 3    to consider the ANDA as it stands.
 4              THE COURT:  Well, and then this is both the NDA
 5    and ANDA?
 6              MR. BLACK:  Well, no, because there's no
 7    relevance to the NDA to infringement or validity.  You don't
 8    have to make --
 9              THE COURT:  Hold on.  There's no relevance.  I
10    thought there was relevance because it has got to be --
11    you're listing the patent.  You're asserting that the ANDA
12    product reads, that the NDA product reads on the patent.
13              MR. BLACK:  Well, we're not required to prove
14    that.  I mean, the --
15              THE COURT:  Isn't that -- I thought that's the
16    whole triggering device.  In order to get ANDA --
17              MR. BLACK:  Right.  But we don't have to prove
18    it.  We listed our product on the Orange Book.
19              THE COURT:  Well, I'm not saying you have to
20    come in and prove it here in court.
21              MR. BLACK:  Yes.
22              THE COURT:  I'm saying to have jurisdiction, the
23    starting point is that you list these patents in the FDA and
24    say that our product, the NDA, reads on these patents.
25    That's what gives rise to Hatch-Waxman jurisdiction in the
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1   first instance. Right?

2   MR. BLACK: Yes. Yes.

3   THE COURT: Okay. I just wanted to make sure.

4   MR. BLACK: Yes. I'm just saying they've been

5   conflating the infringement, validity and NDA filing

6   evidence for rhetorical purposes, but for purposes of how

7   this is going to be reviewed in the Federal Circuit, the

8   only issues are does their product infringe under standard

9   infringement analysis, and, B, is the patent valid and

10   enforceable? Neither of those questions entail any analysis

11   of the NDA. It's their product.

12   THE COURT: So the only thing is, and this

13   is what strikes me, is that you're saying that your

14   product, when I figure out what your product is for the

15   NDA, it's the most current version that has been approved by

16   the FDA.

17   MR. BLACK: Right.

18   THE COURT: Right. So when I look at the ANDA

19   that is at issue here and figure out what the product is, I

20   guess I ought to be looking at what's the most current

21   version of the product that's before the FDA.

22   MR. BLACK: Well --

23   THE COURT: That seems to be a little bit at

24   odds with what your experts were saying.

25   MR. BLACK: I don't think so. I don't think so

1   at all, Your Honor. The issue for infringement, I'm not

2   trying to be -- maybe I'm being a little obtuse today. I

3   just don't quite understand where you're coming from.

4   The infringement analysis is if they make the

5   product that they proposed in the ANDA, their current ANDA

6   specs, not what they may have filed at the beginning, but

7   their current ANDA specs, if they make that product and sell

8   it, will it infringe our patent? That's the infringement

9   analysis.

10   THE COURT: Right. As I understand it, it's

11 undisputed as a factual record, and please correct me if I'm

12 wrong, that the current version of the product is made

13 pursuant to the optimized manufacturing process. Right?

14   MS. WACKER: Yes.

15   MR. BLACK: That is what --

16   THE COURT: Which doesn't cover SVA1. Right?

17   MR. BLACK: That is not right. I don't agree

18 with that at all, Your Honor.

19   THE COURT: Okay.

20   MR. BLACK: They're still representing that

21 as the exhibit batch, as the registration batch, the

22 three critical batches they had to file to get this

23 approved, and the data from SVA1 is still part of the

24 process, if they meet the release spec on SVA1, they can

25 sell it tomorrow.

Park - direct

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1              THE COURT:  Okay.

2              MR. BLACK:  If it expired --

3              THE COURT:  We'll just have argument on that.

4              MS. WACKER:  Okay.

5              THE COURT:  We'll flesh it out.

6              MS. WACKER:  I disagree with those statements.

7              THE COURT:  Let's then go forward.

8              MS. WACKER:  Okay.  Eagle calls Dr. Park.

9                 ... DR. KINAM PARK, having been duly

10   sworn/affirmed as a witness, was examined and testified as

11   follows...

12              THE COURT:  All right.

13              THE WITNESS:  Good morning.

14              MS. WACKER:  Your Honor, may I proceed?  Your

15   Honor, we have some binders that we need to bring up.

16              THE COURT:  To the witness?  Sure.  Thank you.

17                      DIRECT EXAMINATION

18   BY MS. WACKER:

19   Q.    Good morning, Doctor.

20   A.    Good morning.

21              MS. WACKER:  Your Honor, is it okay to proceed?

22              THE COURT:  Please.

23   BY MS. WACKER:

24   Q.    Could you please introduce yourself to the Court.

25   A.    My name is Kinam Park.  I'm currently a Showalter
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1   distinguished professor at Purdue University.

2   Q.   Can you briefly tell the Court what you will be

3   testifying about today?

4   A.   I'll be testifying today that Eagle's product does not

5   infringe the claims of the asserted patents.

6   Q.   And did you help prepare --

7   A.   I'm sorry. I'm not done. The asserted patents are

8   invalid and the 2014 Vasostrict label is material to the

9   patents.

10   Q.   And did you help prepare any demonstratives to assist

11   with your testimony today?

12   A.   Yes, I did.

13   Q.   Can you briefly provide background of your overview of

14   your educational background?

15   A.   Yes. I obtained my B.S. in pharmacy from Seoul

16   National University in Seoul, Korea, and after serving in

17   the Korean military as a lieutenant, I came to the United

18   States, the University of Wisconsin, Madison, and obtained

19   my PhD in pharmaceutics in 1983, and I did two years of

20   post-doctoral training in chemical engineering before I go

21   to become a professor.

22   Q.   Can you briefly tell the Court about your career after

23   receiving your Ph.D.?

24   A.   I went to Purdue University in 1986. Promoted to full

25   professor in 1994. Since 1998, I have been appointed to the

1   department of biomedical engineering.

2   In 2006, I was promoted to the Showalter

3   distinguished professor of biomedical engineering. In 2001,

4   I started a company called Akina Incorporation, and

5   presently, I serve as the president of the company.

6   Q.   And what is Akina Incorporation?

7   A.   Akina Incorporation is a company that sells specialty

8   polymers that are used for a variety of formulations and

9   biomedical devices and currently, we have contracts with the

10   FDA and many other companies.

11   Q.   We've heard yesterday that this case is about peptide

12   formulations. What experience do you have with peptide

13   formulations?

14   A.   Yes. Over the years I have made many peptide

15   formulations, protein formulations, especially for

16   long-acting injectable formulations. For peptide

17   formulations, I made leuprolide, goserelin, octreotide,

18   triptorelin. Protein formulations, I made insulin

19   formulations, botulinum toxin, which is commonly known

20   as botox, Concanavalin A, lysozyme, fibrinogen and

21   transferrin.

22   Q.   In your binder, you have DTX-282-A. Is this a current

23   and accurate copy of your CV?

24   A.   Yes except a few more publications I added in.

25   MS. WACKER: Eagle tenders Dr. Park as an expert

Park - direct

1   in pharmaceutics and chemical development.

2   MR. BLACK: No objection.

3   THE COURT: All right.

4   BY MS. WACKER:

5   Q.   Let's turn to noninfringement. What do you understand

6   to be the asserted claims in this case?

7   A.   The '209 patent, claims 1, 4, 5 and 7, and the '785

8   patent, claims 1, 5 and 8.

9   Q.   And here we have the defendants' claims from the '209

10   and '785 patent. Can you just generally give an explanation

11   of what those claims are directed to?

12   A.   Well, the '209 patent is related to a method of

13   treatment using specific Vasopressin formulations having a

14   specific impurity profile and '785 patent relates to

15   pharmaceutical compositions of Vasopressin formulation with

16   their profile.

17   Q.   And why is that an X next to the pH 3.7 to 3.9

18   formulation element here?

19   A.   As we heard yesterday, Eagle made a formulation having

20   3.4 to 3.6, so Eagle does not make a formulation having pH

21   3.7 to 3.9.

22   Q.   And what legal framework did you apply in coming to

23   your opinions in this case with respect to infringement?

24   A.   I applied the legal framework that follows. Direct

25   infringement, accused direct infringer must literally

1   perform each step of the claimed methods. This is the '209

2   patent and an accused direct infringer must make, use, sell,

3   offer to sell, or import claimed compositions in the U.S.,

4   the '785 patent.

5   Eagle is not making formulation with the '209.

6   For indirect infringement, induced infringement, normally,

7   direct infringement by a third party. Knowingly induce

8   direct infringement by a third party.

9   Q.   Okay. Now, did you hear the testimony of Dr. Kirsch

10   yesterday with respect to infringement?

11   A.   Yes, I did.

12   Q.   And do you agree with his opinion that Eagle's

13   products, if approved and sold, will infringe the asserted

14   claims in this case?

15   A.   No, I do not.

16   Q.   All right. So let's turn to the first part of your

17   opinion. What is your first opinion with respect to

18   noninfringement?

19   A.   My first opinion is that Eagle's ANDA requires a

20   noninfringing pH, so it will not go to 3.7 to 3.9.

21   Q.   And here on slide 10 we have DTX-131. What is

22   DTX-131?

23   A.   This is Eagle's ANDA submission to the FDA.

24   Q.   And if we look at this ANDA submission, on the

25   left-hand column, the first one that's highlighted that says

Park - direct

1   Vasopressin injection, USP, what do you understand that to

2   be representing?

3   A.   This is Eagle's proposed generic product to the

4   Vasopressin injection.

5   Q.   And then next to that where it states Vasostrict,

6   Vasopressin injection, initial NDA, approved April 17, 2014,

7   what is that representing?

8   A.   I now understand this is a reformulated Vasostrict.

9   Q.   The middle column?

10 A.   Middle columns is Original Vasostrict.

11 Q.   Sorry. Let me make sure we have this accurate for the

12 record. So the middle column is highlighted Vasostrict

13 injection, initial NDA approved April 17th, 2014. What is

14 that column representing?

15 A.   This column represents the RLD, which is known as

16 reference listed drug, and Eagle is making copy of this

17 original Vasostrict.

18 Q.   So the middle column, can we agree that's original

19 Vasostrict?

20 A.   Yes. Again, we talk about either original Vasostrict

21 or 2014 Vasostrict.

22 Q.   Okay. Are there any differences here between Eagle's

23 proposed Vasopressin injection product and the original

24 Vasostrict product that was approved in April 2014?

25 A.   There was no difference. That's the point of this

1   ANDA.   As we can see, condition of use is exactly the same.

2   Active ingredients, exactly the same.   Inactive ingredients,

3   water for injection, acetic acid, chlorobutanol, exactly the

4   same.   That's the whole point of the product.

5   Q.   You mentioned RLD.   What is an RLD?

6   A.   RLD is again reference listed drug.   Whenever new drug

7   applications are approved, that drug automatically becomes

8   RLD because then generic companies will make a copy of the

9   product.   That's why they call it reference listed drug.

10   Q.   Okay.   And now on the right-hand column, the one

11   that's not highlighted, Vasostrict, Vasopressin injection,

12   supplement three, approved March 21, 2016, what do you

13   understand that to be representing?

14   A.   That is again reformulated Vasostrict, which Par

15   revised from the original Vasostrict.

16   Q.   And is Eagle using that reformulated formulation as an

17   RLD?

18   A.   No.   Again, at the bottom highlighted, Eagle specifies

19   the original version of Vasostrict, approved April 17, 2014,

20   as the RLD.   It's clear.

21   Q.   All right.   And does the reformulated Vasostrict have

22   the same pH information as the original Vasostrict and

23   Eagle's product?

24   A.   No.   We can compare at the bottom, second from the

25   bottom row.   I can see that acetic acid should be adjusted

1   to 3.4 to 3.6 original Vasostrict. The right side says

2   sodium acetate buffer to adjust pH to 3.8. There's a

3   difference in pH. Also, reformulated Vasostrict does not

4   contain chlorobutanol.

5   Q.   All right. Slide 11, we have an excerpt from DTX-327

6   at page one. What is this document, Dr. Park?

7   A.   This is, again, ANDA documentation to the FDA.

8   Q.   Okay. And what is being shown here on page 1 of

9   DTX-327?

10   A.   This shows that the stability is 3.4 to 3.6.

11   Q.   This is for Eagle's proposed ANDA product?

12   A.   Yes, it is.

13   Q.   And what is a release specification?

14   A.   Again, it clearly indicates 3.4 to 3.6.

15   Q.   What is a release specification?

16   A.   Release specification is pH before they release the

17   product.

18   Q.   And what is a stability specification?

19   A.   A stability specification is the specification that

20   should be met during the shelf life.

21   Q.   And so based on these specifications, what is your

22   understanding of what Eagle is telling the FDA about its

23   proposed ANDA products, the pH of its proposed ANDA products

24   through its shelf life?

25   A.   Well, Eagle is reporting to the FDA that Eagle's

1   product will maintain pH of 3.4 to 3.6 throughout its shelf

2   life.

3   Q.   And based on the information you have reviewed about

4   Eagle's product, would you expect Eagle's product to meet

5   these specifications?

6   A.   Yes. All the data we have from yesterday, all the

7   pH we have seen, yes, they are between 3.4 and 3.6, so I

8   say that Eagle's product will maintain pH between 3.4 and

9   3.6.

10   Q.   At the bottom of the slide, there's also reference to

11   DTX-678, page 2, and PTX-1427 at page 1. Do you understand

12   that these are just supplemental ANDA submissions that

13   contain the same specification?

14   A.   Oh, yes. Eagle submitted the revised updated version

15   all the time, but this table, the information remained the

16   same.

17   Q.   All right. Now, did you look at the data for Eagle's,

18   the pH data for Eagle's proposed product?

19   A.   Yes, I have.

20   Q.   Okay. Did you look at all of the pH data that is

21   available for the batches that have been made of Eagle's

22   ANDA product?

23   A.   Yes. I think everybody saw it, too. We have pH data

24   from batch 1 all the way to batch 17.

25   Q.   And do you agree with Dr. Kirsch, that the data that

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1   Eagle has on the batches that have been made would establish

2   infringement of the asserted claims?

3   A.   I don't. We all saw the data. Data does not support

4   that.

5   Q.   And approximately how many pH measurements have been

6   taken?

7   A.   Roughly, I think around 350.

8   Q.   I want to talk a little bit about what batches have

9   been made, and so here on slide 14, you describe a number of

10   the batches and what they are called in the FDA documents,

11   so maybe we could talk about that a little bit.

12   On the left-hand side here at the top, there is

13   a discussion of registration batches, SVA1 through 3. What

14   do you understand those to be and when were they

15   manufactured?

16   A.   Those are the batches that Eagle or any company used

17   to report to the FDA that this is a registration batch,

18   that we're going to prove that we can present the final

19   product.

20   Q.   And so the registration batches, were those made

21   according to the current proposed commercial process?

22   A.   No. Actually, that's not. That's why I have a

23   dotted line there to indicate the manufacturing changes.

24   So they actually at the time submitted to the FDA, it was.

25   Now that the manufacturing process changes, especially for

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1   pH, the batch 1 does not represent pH of the final product.

2   Q.   And below that, you have characterization batches,

3   SVA4 through 6. What are the characterization batches and

4   when were they manufactured?

5   A.   Well, Eagle still made those representative batches.

6   FDA has some question, so Eagle made new characterization

7   batches to provide answers to the FDA.

8   Q.   And when were those manufactured?

9   A.   Those were manufactured in March 2019.

10   Q.   And then you have a dotted line here where it says

11   manufacturing change. Were those two, the six batches,

12   registration and characterization batches, made according to

13   the new optimized manufacturing process?

14   A.   Right. So as I mentioned, optimization batches were

15   made by using new manufacturing changes so that the pH can

16   be more represented between 3.4 and 3.6.

17   Q.   So in your opinion, would batches 1 through 6 that

18   were made with the old manufacturing process be

19   representative of the pH of Eagle's proposed ANDA products?

20   A.   No. Batch, registration batches still representative

21   of some properties of the product, but not pH. So pH is

22   represented by optimization batches.

23   Q.   Okay. So now below the manufacturing line change,

24   there's optimization batches 7 through 9. When were those

25   manufactured?

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1   A.   They were made in July and August of 2019.

2   Q.   And were those made with the optimized manufacturing

3   process?

4   A.   Exactly. That is why it says optimized batches.

5   Q.   The PPQ batches, 11 through 13, when were they

6   manufactured?

7   A.   November and December 2020.

8   Q.   Were those manufactured with the optimized process?

9   A.   Yes. They are all prepared using manufacturing

10   changes.

11   Q.   And in your opinion, would batches 7 through 9 and 11

12   through 13 be representative of the pH of Eagle's proposed

13   ANDA product?

14   A.   Oh, yes. As I mentioned before, pH of the final

15   product is represented by the optimization batches or since

16   then.

17   Q.   All right. Now, on the right-hand side of the slide,

18   there's some information about different parameters that are

19   used for the stability testing. Could you explain what is

20   listed here?

21   A.   Yes. For many studies, many samples are collected,

22   samples in vials. One is at room temperature. The other is

23   refrigeration temperature. The others, the bridging study,

24   the refrigeration temperature followed by room temperature.

25   In each storage condition, they are stored in

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1   upright and inverted storage. Inverted storage is necessary

2   because solution has contact with the rubber stopper. You

3   want to make sure that rubber stopper does not release

4   anything toxic. So this is to study nothing released from

5   the rubber stopper.

6   Q.   Now, are you aware of other batches that Eagle made

7   that were not placed on stability?

8   A.   Yes. They are placed on the slide, batch 10, 14, 15,

9   16 and 17 were made.

10   Q.   Okay. And for the batches that were rejected or

11   aborted, do you have an understanding as to whether they

12   were rejected or aborted for reasons relating to pH?

13   A.   No. Some of them was because the API was not pure, so

14   they were rejected. The fact that they were rejected or

15   aborted means Eagle is using good manufacturing process.

16   There's a good quality control in place. So if the batch

17   does not meet the criteria of each step of the process, they

18   are not going to release the batch.

19   Q.   All right. So on slide 16 here, we have some

20   information from DTX-993, which is the summary exhibit on

21   page 5 of that. First of all, can you just look at DTX-993

22   in your binder?

23   A.   Yes.

24   Q.   And what is this document?

25   A.   This is a table containing all the pH measurements,

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1   all three different conditions, upright and inverted

2   conditions.

3   Q.   Okay. And did you examine -- there's a number of DTX

4   numbers cited on the pages of this DTX-993. Do you have an

5   understanding of what those are?

6   A.   Yes. Those are the reports on the pH and report,

7   characterization report of each batch at each time point and

8   there are several laboratory notebooks, so all of these

9   numbers indicate that particular characterization,

10   particular batches, particular time and laboratory

11   notebooks.

12   Q.   And did you review those documents and the data

13   contained in DTX-73?

14   A.   Yes. I compared the actual pH data on the document

15   and I confirmed that it's correct.

16   Q.   Going back to slide 18, what data is being shown here?

17   A.   This is all pH measurement data of the room

18   temperature data.

19   Q.   Okay. In your opinion, based on the room temperature

20   data, would any of that establish infringement of the

21   asserted claims?

22   A.   Well, as we all can see, all of the pH values are

23   between 3.4 and 3.6 and none of them goes to the claimed

24   range of pH 3.7 to 9.

25   Q.   Did you hear any testimony from Dr. Kirsch yesterday

Park - direct

1   that any of the room temperature data for Eagle's proposed

2   product would establish infringement?

3   A.   I don't believe so.

4   Q.   And looking at the optimized batches at the bottom

5   here, the pH data, do you see any sort of trend with respect

6   to this data?

7   A.   Well, if you plot it on a graph paper, you may see it

8   a little more clearly, but from this table, in the beginning

9   you start with about pH 3.50 and you look going down to

10   12 months, about 3.37, 3.39. So it looks like a trend is

11   literally going downward.

12   Q.   All right. So slide 17, there's more information from

13   993, pages 7 and 9. This is the bridging study data. Can

14   you explain what a bridging study is?

15   A.   Again, bridging study is initially vials are stored in

16   a refrigeration temperature for a period of time and moving

17   to room temperature. That's called bridging study.

18   Q.   And in your opinion, would any of the data relating to

19   the bridging study establish infringement of the asserted

20   claims?

21   A.   It was to see the data. None of the data shows

22   outside 3.4 to 3.6.

23   Q.   Did you hear any testimony from Dr. Kirsch yesterday

24   regarding any of the bridging study data and that would

25   establish infringement of the asserted claims?

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1   A.   I don't think so.

2   Q.   And I think I forgot to ask this. On these slides and

3   on some of the demonstratives that we looked at yesterday,

4   the batches are indicated in red and blue. What does the

5   red and blue represent?

6   A.   Again, I think all the tables show the red means

7   batches were prepared before manufacturing change and blue

8   highlighted batches are batches prepared after manufacturing

9   change.

10   Q.   All right. So let's take a look at slide 18.

11   It has data from 993, pages 1 and 13. What is being shown

12   here?

13   A.   This is pH measurements of the samples through the

14   refrigeration temperature.

15   Q.   On the top, the top batch here is upright; is that

16   right?

17   A.   Yes. That's the one upright position.

18   Q.   The top right-hand corner, there's the box that has

19   the highlighted entries. What do you understand those to

20   be?

21   A.   All right. When they measured the pH of the samples,

22   the initial pH measurement was 3.69, so that was out of

23   specification, so at the time measured one more time the

24   same sample and that was 3.75. Again, that was out of

25   specification. They pulled another five vials and measured

1   pH again.   That was 3.68.   That's why we have three values.

2   Q.   Focusing on the top, the batches in red, are there any

3   other pH measurements that are out of the 3.4 to 3.6

4   specification for those batches?

5   A.   No.   I think what I'd like to highlight here is that

6   even without the manufacturing change, all the pH values

7   remain between 3.4 and 3.6.   Only one, batch 1, upright

8   position at 24 months at the end of expiry shows one out of

9   specification pH measurement.

10   Q.   And now looking at the data in blue, the optimization

11   and PPQ batches, what is your opinion with respect to that

12   data?

13   A.   I think the data clearly indicates one thing clear.

14   First of all, before manufacturing changes, if you look in

15   data at the red highlighted batches, the pH there is between

16   3.4 and 3.6 except the one at 24 months, but the values are

17   around, literally fluctuate a lot, because as you can see

18   from 3.44 to 3.64, et cetera, but if you look at the blue

19   highlighted batches, all the data around 3.5, 3.51, 3.52.

20   None of the data is actually as high as the one we observed

21   in the batch 1.

22   Q.   One quick thing.   On the bottom, PPQ batch, the

23   initial 3.52 value.

24   A.   I'm sorry.   Which one?

25   Q.   For the initial value, for SVA11.   Do you see that?

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1 A.   Yes.

2 Q.   You understand there were six measurements that were

3 made for SVA11, six pH measurements that were taken for

4 SVA11?

5 A.   Six pH.

6 Q.   Can we get DDX-7-1 on the screen? I can't read that

7 one. Can we get DDX-7-3 on the screen?

8 A.   Oh, that one? Yes, I'm sorry.

9 Q.   Okay. And so for the initial measurements for SVA11,

10 you understand there were six measurements that were taken

11 for the release testing and the initial pH?

12 A.   Yes. First three measurements were done on

13 November 30th and another technician at AMRI measured the

14 same again. That's the second one.

15 Q.   All right. But on this slide, the value, 3.52 is

16 including. Do you have an understanding as to why that 3.52

17 is included here?

18 A.   Because all six measurements were for the same sample,

19 so they averaged all six measurements. That is 3.52.

20 That's the actual value.

21 Q.   Is that the value that Eagle and AMRI have recorded

22 for the initial measurements for that batch?

23 A.   Yes, that's correct.

24 Q.   And how long does the data, how long has the stability

25 data been taken for SVA7 through 9?

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1   A.   Up to 18 months by now.

2   Q.   All right. How long do we have stability data for

3   SVA11 through 13?

4   A.   Up to six months.

5   Q.   So based on all of the refrigerated data we have here,

6   what is your opinion as to whether or not some vials of

7   Eagle's ANDA products will have a pH in the infringing range

8   3.7 to 3.9?

9   A.   I can rely only on data. As you can see, data

10   indicates all the values around 3.50. 3.52 or 3.51. So

11   none of the data go out of their range, so I expect that pH

12   will remain between 3.4 and 3.6.

13   Q.   And on slide 19, the pH data, can you explain what's

14   being represented here?

15   A.   This is a graphical representation of the pH measured

16   for refrigerated batches before and after manufacturing

17   change.

18   Q.   This is the refrigerated data?

19   A.   Yes.

20   Q.   At the top, there's a plot of the registration and

21   characterization batch data, so that's SVA1 through 6.

22   A.   That's right. SVA1 through 6.

23   Q.   And on the bottom, there's a plot of the data for the

24   optimization and PPQ batches 7 through 9 and 11 through 13?

25   A.   Yes.

1   Q.   Okay. And what is your opinion? Can you explain what

2   this data shows?

3   A.   Yes. Previously we saw the table. The table is

4   sometimes difficult to see the trend, but the figures

5   clearly indicate the difference between batches prepared

6   before and after manufacturing changes.

7   Now, at top, the red highlighted one, before

8   manufacturing changes. As you can see, again, except the

9   one at the end of 24 months, all the values remain between

10   3.4 and 3.6. You can see data points are a little widely

11   fluctuating. On the other hand, if you look at the pH at

12   the bottom, all the pH values are closely around 3.50, and

13   that is exactly the goal that Eagle had. What they reported

14   to FDA are to make around 3.50. That's what the result

15   shows, that Eagle meant.

16   Q.   All right. So let's talk about that optimized

17   manufacturing process. First of all, here on the screen we

18   have DTX-331, page 9. When that data point for SVA1 was

19   obtained, what do you understand Eagle did, Eagle and AMRI

20   did in response to that?

21   A.   Well, when Eagle and AMRI received the one data pH

22   reading, out of specification, they had to investigate, they

23   had to understand why that particular time point was out of

24   specification. So they did, as you highlight there, out of

25   specification investigation was promptly conducted.

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1   Q.   Okay. And what was the cause, the root cause

2   determined for that?

3   A.   Again, that's Eagle reported to the FDA. They went

4   through all the potential factors. It's not the API itself.

5   It's not acetic acid. So they concluded the specification,

6   conclude that the root cause of the out of specification was

7   determined to be batch SVA001 was released at the upper

8   limit of the pH specification, which is the release value of

9   3.64.

10   Q.   And did Eagle do anything in response to the

11   determination?

12   A.   As soon as they found out the root cause, they did

13   manufacturing changes to correct the problem, and that's why

14   they further described that in order to provide greater

15   confirmation of consistent product quality through the

16   proposed expiry period, the manufacturing in-process

17   controls were subsequently optimized to assure tighter

18   control of pH. Here, trying to control pH during

19   manufacturing.

20   Q.   All right. So let's talk about those changes.

21   What is the demonstrative here generally? What

22   is being shown here on slide 22.

23   A.   This is a schematic presentation of Eagle's

24   manufacturing process, so that everyone can understand.

25   Q.   And so on the left-hand column, the one we can see

1   that's not shaded out, what's that step? What's being

2   represented here?

3   A.   Well, the left step is the beginning of the

4   compounding and compounding is a process where you mix

5   ingredients to make a final formulation. That's called

6   compounding.

7   The second is pH adjustment. The reason we

8   call it adjustment, we start with the water. Start with the

9   water and add Vasopressin and chlorobutanol. To make a pH

10   3.4 to 3.6, we had to adjust the pH. That's why we add

11   acetic acid. Acetic acid is vinegar. Vinegar mixes with

12   water very well. You just add acetic acid to 35-liter tank

13   and stir to make it homogeneous pH around the tank.

14   Q.   On the right-hand side there's a 95 percent QS and a

15   100 percent QS. What does that mean?

16   A.   So this batch starts with 35 liters. 35 liter as

17   counsel mentioned in opening statement about Gatorade with

18   the cooler, it's about one foot diameter and about two feet

19   high. So it's quite a big size, nine gallons. So 35

20   liters, you fill the water up to 95 percent, so 95 QS,

21   quantity sufficient to fill 95 percent, and then add acetic

22   acid and adjust the pH, pH adjustment to make a pH around

23   3.42 to 3.49.

24   Q.   All right. And then once -- let's start with the

25   95 percent QS. Once the QS has been adjusted to 3.42 to

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1   3.49, you have arrows, you're going to stabilization?

2   A.   This is Eagle's proposed manufacturing change to

3   ensure how to control the manufacturing, Eagle implemented

4   so-called new pH stabilization step. It's just basically

5   continuing mixing, so pH remains between 3.42 and 3.50.

6   Q.   Is this all done again at the 100 percent QS?

7   A.   Right. If the pH is met, then you add more water to

8   make 100 percent QS, meaning 35-liter, hundred percent

9   volume, and then measure the pH again, the pH adjustment,

10   stabilization step again.

11   Q.   At the bottom of this slide there's reference to

12   DTX-324, the proposed commercial manufacturing batch

13   record. Is that where you obtained your information to

14   prepare this?

15   A.   Yes. The batch manufacturing record shows all the

16   diagrams. I just put into some figure so we can easily

17   understand.

18   Q.   All right. Let's talk in a little bit more detail

19   about the adjustment and stabilization steps. On the

20   left-hand side here, at zero time, that's the adjustment

21   step you were talking about where acetic acid is added?

22   A.   Yes. That's the beginning when you add acetic acid.

23   As I mentioned, acetic acid is vinegar which mixes with

24   water very well. Mix less than ten minutes to have

25   homogeneous mixing.

Park - direct

1   Q.   How is it being mixed?

2   A.   Sorry?

3   Q.   How is it being mixed?

4   A.   Oh, every solution in this quantity, you have to have

5   a propeller used to put from the top to stir.

6   Q.   And then so it's mixing at ten minutes and then what

7   happens at time 20 minutes?

8   A.   So you, after adjusting pH, and at 20 minutes of

9   mixing, you collect the sample from the bottom of the tank

10   and measure the pH again, and then continue to mix for

11   another ten minutes. After mixing, you collect the sample

12   again from the bottom and measure the pH again.

13   Q.   Why would you collect the sample from the bottom of

14   the tank?

15   A.   Acetic acid is on the top. The top has enough acetic

16   acid where you can stir to make that acetic acid go down to

17   the bottom and homogeneously mix.

18   Q.   And so when the measurement is taken at 20 minutes,

19   what pH range does that need to be in?

20   A.   As shown at the top, should have pH reading between

21   3.42 and 3.50.

22   Q.   And then what pH range does the sample at 30 minutes

23   maintain?

24   A.   So when we measure pH at 20-minute sample and

25   30-minute sample, between 3.42 to 3.50 and also two pH

1   readings should be within .03 pH unit difference.

2   Q.   So what happens if at time 30 minutes, the pH of the

3   sample is 3.53?

4   A.   Then you go all the way back to the pH assessment and

5   start the process again. Actually, that happened in Eagle's

6   record. It happened three or four times.

7   Q.   And did they go back and do the pH adjustment steps?

8   A.   Right. That's what the whole process is. If pH is

9   out of spec, you go all the way back to pH adjustment and

10   start all over again.

11   Q.   But what happens if you have a measurement at time

12   20 minutes that is 3.42 and then at time 30 minutes, it's

13   3.49. So they are both within the 3.42 to 3.49

14   specification but they are not within .03 of each other?

15   A.   As long as they are meeting the specification, the two

16   readings are not within .03. You just continue to stir. So

17   in that case you go back to second step, not less than

18   ten-minute stirring. So you continue to stir another ten

19   minutes and measure again the samples and another ten-minute

20   interval to see the difference in pH reading.

21   Q.   And what would be the scientific objective of doing

22   this process, of stabilizing the formulation?

23   A.   Complete homogeneous mixing. As I mentioned, acetic

24   acid is water soluble, so you can mix very well, but still

25   to ensure we can mix, continue mixing for hours.

1   You have a 35-liter coffee and you add the

2   sugar. You just completely mixing for hours. I can always

3   guarantee the sugar dissolves and sugar dispersed throughout

4   the 35-liter coffee container. That's what it's trying to

5   do.

6   Q.   So in your opinion, what is the impact on Eagle's

7   proposed ANDA product of having a pH stabilization step, an

8   adjustment step as set out here?

9   A.   Again, the goal was to have a narrower tighter pH

10   reading. That's exactly what they did. Again, acetic acid,

11   water soluble, that Eagle implemented let's mix more. Let's

12   mix hours so that we have a full complete mixing of acetic

13   acid throughout the whole tank. That's what Eagle has done.

14   That's the result we have seen.

15   Q.   So in your opinion, would Eagle's product be

16   homogeneous?

17   A.   I cannot think otherwise.

18   Q.   Have you looked at any, of the batches 7 through 9 and

19   actually all of the batches that have been made with the

20   optimized process to see approximately how long this process

21   has taken for Eagle for those batches?

22   A.   Yes. I received the documents, batch 7 through 17,

23   and some batches you had to go through a step twice or

24   three times, sometimes adjustment step. So overall, average

25   time to finish adjustment, stabilization, it was about three

1   hours.

2   Q.   Okay. So you have DTX numbers cited on the slide.

3   Are DTX-333, 334, 845, 867, 889, 913, 938 and 941, are those

4   the batch records?

5   A.   Yes. Those are batch records I saw where they discuss

6   how much time it took for pH adjustment step. If the

7   specification was not met, they had to do it again and

8   establish those steps, too.

9   Q.   You mentioned in your opinion this would generate a

10   homogeneous solution. Does that mean that any pH

11   measurements that are take even for stabilization for these

12   products will be exactly the same?

13   A.   No. It's a human thing. Human, also mechanical

14   thing. Even if you measure same sample, it's not going to

15   be exactly the same, but around the same value.

16   Q.   All right. So now going back to the overall

17   commercial manufacturing process, what is being shown here

18   in the middle section?

19   A.   Now, if the pH adjustment and pH stabilization samples

20   are done successfully, then you go next to the example for

21   pre-filtration. And filtration, here is the filtration to

22   point to the filter to remove all of the bacteria and just

23   make it clearer.

24   Q.   And what is the specification for the pre-filtration

25   samples measured here on the bottom on slide 24?

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1   A.   3.42 to 3.54.

2   Q.   And how is that sample taken?

3   A.   Oh, again, the sample is taken from the bottom of the

4   tank.

5   Q.   And then on the right-hand side, what is being shown

6   here?

7   A.   So once you measure the pH before filtration and go

8   through the filtration steps and then the solution is filled

9   into individual vials.

10   Q.   Approximately how many vials are filled from this tank

11   of one batch?

12   A.   35 liter, they make around 26,000 vials, because even

13   though it's a one ml sample, they actually add in 1.16 ml.

14   So it is about 26,000 bottles and they reserve about 5,000

15   milliliter as a reserve.

16   Q.   And then below this, you have post filtration samples.

17   Are those samples of the vials?

18   A.   Yes.   They are all samples.   At this point everything

19   is filled into the vials and the vials are collected and all

20   the samples are measured from the vials.

21   Q.   Okay.   And so let's take a look at the next slide.

22   That would be helpful.   Where do you understand the post

23   filtration samples to come from?

24   A.   Again, after filtration, you start filling the

25   vials and in the process, first 90 vials are collected to

Park - direct

1   measure post filtration pH measurements. And you can

2   have a random sampling, 90 for samples, but if the stability

3   study is necessary, then you can select random samples from

4   the beginning, the middle and end of the capping process.

5   Q.   And this is slide 25. And all of these vials, are

6   they all filled at the same time?

7   A.   Yes. They are filled not exact same time, but around

8   the same time, same day, the same place.

9   Q.   So you are not like leaving this tank full of stuff

10   and taking a measurement from it six months later for

11   stability, 18 months for stability, that's all done in the

12   vials?

13   A.   Yes. You collect the samples of the vials. Sample

14   means vials and store it in the refrigerated temperature or

15   room temperature and collect those five vials at each time

16   point and measure, and once you measure, obviously, you

17   cannot use it again, you discard. The next time point, you

18   collect another five vials for measurement.

19   Q.   You mentioned that you select five vials for

20   measurement. Why would five vials be selected for

21   measurement?

22   A.   Again, as I understand, the pH probe is actually

23   large. The one I have been using in all of my research. So

24   one ml vial is small, so opening, sometimes it cannot go in.

25   It's routine to pull different vials with sufficient volume

Park - direct

1   so the pH probe. pH probe is basically glass. You have to

2   submerse enough to have an accurate reading of a pH.

3   Q.   And then so what is done with those samples or those

4   vials? Are they used for the next pH sample test?

5   A.   No. One measurement, that's the end. You use another

6   new vial for next measurement.

7   Q.   All right. So let's go to slide 26. Can you

8   generally describe what's being shown here?

9   A.   This is just to compare the difference in

10 manufacturing process between registration batches, batch 1

11 through 3, and the proposed commercial product, which is

12 optimization batches.

13 Q.   And focusing on the first part, registration batches 1

14 through 3, what was the pH specification for the adjustment

15 stage for the acetic acid added to the tank?

16 A.   Right. The pH was 3.4 to 3.6.

17 Q.   And what was the target?

18 A.   The target is 3.5.

19 Q.   And now for the proposed commercial products, what is

20 the pH adjustment specification?

21 A.   Now, here, as we discussed before, when Eagle was out

22 of specification of pH reading at the end of 24 months, they

23 conducted an investigation and the root cause was incomplete

24 mixing. So they started making sure. So they adjust the pH

25 to 3.4 to 3.49 and target 3.45, and then they conducted a

Park - direct

1   new pH stability step.

2   Q.   Okay. So was there a pH stabilization step in the

3   registration batch manufacturing?

4   A.   No. That is the point of slide 26, because it was not

5   there and that's why pH might have been fluctuating so much

6   so that Eagle implemented a new manufacturing process that

7   includes pH stabilization data.

8   Q.   And what is the pH specification for the stabilization

9   test?

10   A.   3.42 to 3.50, but as you can see, it's much lower and

11   narrower than the pH specification of the registration

12   batch.

13   Q.   All right. On slide 28 we have excerpts from DTX-323

14   at pages 5 and 9 through 10. Is this where you obtained the

15   specification information for the, that was used for the

16   registration batches and that is in the proposed commercial

17   batch?

18   A.   Yes. This is the same information I used.

19   Q.   All right. And looking on the right-hand side here,

20   pages 9 through 10, is there any rationale or specification

21   that Eagle provided to the FDA as to why they changed their

22   pH specification and added the stabilization step?

23   A.   Well, yes. We went through the slide already, but

24   here again, Eagle informed the FDA, the exact reason is to

25   assure tighter pH control throughout manufacturing process.

1   Q.   Now, going down to the next in-process specification,

2   the first one, in-process pre-filtration. Now, that was

3   that middle column where the sample is taken after acetic

4   acid is no longer added and before the vials are filled; is

5   that right?

6   A.   Right.

7   Q.   Okay?

8   A.   Pre-filtration, yes.

9   Q.   So that was that middle column of the tank?

10   A.   That's right.

11   Q.   All right. And what was in-process pre-filtration

12   specification for the registration batches?

13   A.   Specification was 2.5 to 4.5 with a target of 3.4 to

14   3.6.

15   Q.   What is the in-process pre-filtration proposed

16   specification for the proposed commercial product?

17   A.   Obviously, much narrower. 3.42 to 3.54.

18   Q.   Below that, the in-process post filtration. Now,

19   that's testing of the vials; is that right?

20   A.   Yes, that's right.

21   Q.   And what was the in-process post filtration for the

22   registration batches?

23   A.   Again, 2.5 to 4.5 with a target of 3.4 to 3.6.

24   Q.   And what is the in-process post filtration

25   investigation for the proposed commercial product?

Park - direct

1   A.   3.42 to 3.54.

2   Q.   And on slide 30 you have again an excerpt from

3   DTX-323, pages 12 to 13. This is where you obtained the

4   specification information from the previous slide with

5   respect to the registration batches and the intended

6   commercial product batches?

7   A.   That's correct.

8   Q.   Now, did you look at any of the in-process pH

9   measurements for SVA1?

10   A.   Yes.

11   Q.   Here, on the top of the slide is that same excerpt

12   from 323 that we just had and on the bottom is DTX-134,

13   which is the certificate of analysis for SVA1 at page 1.

14   What was the pre-filtration measurement for

15   SVA1.

16   A.   As you can see, 3.7, that meets the specification for

17   batch 1 at the time.

18   Q.   And what was the post-filtration pH measurement?

19   A.   3.6.

20   Q.   So would both of those pH measurements have met the

21   specification in place at the time SVA1 was manufactured?

22   A.   Right, at the time.

23   Q.   And let's start with the first one. Would the

24   pre-filtration measurement of 3.7 have met the specification

25   of the intended commercial production batches?

1   A.   Clearly not, because the intent is 3.42 to 3.54, so

2   this would not meet the qualification.

3   Q.   Okay. And would the post filtration measurement of

4   3.6 have met the intended commercial production batch pH

5   specification?

6   A.   Again, not.

7   Q.   So in your view, is SVA1 representative of the pH of

8   the proposed commercial product?

9   A.   No. Again, I mentioned a few times before, we went

10   through, batch 1 represents certain properties of the final

11   product but not pH. pH is represented by batches 7 to 9,

12   optimization batches, after manufacturing using new

13   manufacturing process.

14   Q.   All right. Let's turn to the last section, release

15   and stability. At the time SVA1 through 3 were

16   manufactured, what were the release and stability pH

17   specifications?

18   A.   Well, this is the one we have gone through, 2.5 to

19   4.5.

20   Q.   And for the proposed commercial products, what are the

21   release and stability products?

22   A.   3.4 to 3.6.

23   Q.   And here on slide 33 at the top, do we have an excerpt

24   from DTX-2 at page 1? Is this where you obtained the

25   release and stability specification for SVA1?

Park - direct

1   A.   Yes. As you can see, the lot number, SVA001.

2   Q.   And that was manufactured in March of 2017?

3   A.   Yes.

4   Q.   And your understanding, that was before the patents in

5   this case issued?

6   A.   Yes.

7   Q.   And on the bottom, there's an excerpt from DTX-327 at

8   page 1. This is where you obtained the release and

9   stability information for Eagle's products?

10   A.   Yes.

11   Q.   And we're also citing to DTX-78 and DTX-1427 at page

12   1, the chart, which are the same position and updated ANDA?

13   A.   Yes. I mentioned they are updating the information,

14   but this information remained the same.

15   Q.   Have you seen any information in the batch records

16   that indicate that the post-filtration and release testing

17   samples were taken at the same time and is the same place?

18   A.   Yes. As I show on the slide, you can see that batches

19   7, 8 and 9, they are collected from the same testing area

20   capping area, which means you fill the vials and cap,

21   capping area. You can see the same day, on the same day

22   around the same time and the same place.

23   Q.   I didn't mean to interrupt you. This is slide 34 and

24   on the top, DDX-2-34, that's the proposed batch records

25   we've been discussing?

1   A.   Yes.

2   Q.   SVA7, 8 and 9 were the information maintained for

3   those batch records?

4   A.   Yes.

5   Q.   Why in your opinion does it matter that these vials,

6   these samples are selected at the same time from the same

7   place?

8   A.   Well, because post-filtration and release samples and

9   release samples, they are collected at the same time, so

10   basically, we label them post filtration and samples, but

11   samples are collected the same day, same place, same time.

12   So they actually represent the whole batch.

13   Q.   All right. So did you hear Dr. Kirsch yesterday opine

14   that in his opinion, some vials may be released at 3.64?

15   A.   I heard that.

16   Q.   And do you agree with that?

17   A.   Again, based on the manufacturing process we have gone

18   through and all the data we have here for batch 7 and on, no

19   data indicates that the pH will go to 3.64.

20   Q.   So based on Eagle's optimized manufacturing process

21   that we've just gone through, would you expect to see large

22   variability between different vials of the batch of Eagle's

23   product?

24   A.   No. Again, as we have seen, all the data, pH

25   measurements for the new manufacturing process batches, the

Park - direct

1   pH values are all around 3.50, 3.51, 3.52, so I don't expect

2   they will be above 3.64.

3   Q.   Can I get DDX-7-3.

4   Now, this is -- this is showing all of the

5   post-optimization data?

6   A.   That's right.

7   Q.   In your opinion, does this data demonstrate very wide

8   variability within Eagle's batches?

9   A.   No. I think -- let me be a little more specific here.

10   Dr. Kirsch and Par was talking about batch 11, and they had

11   two data points, 3.47 and 3.57. So there's a .1

12   variability. It's true, it's there, but it is good to

13   remember that all this variation occurs around 3.52.

14   If you have average of 3.57 and 3.52, 3.57 and

15   3.47, all six measurements, 3.52. So this variability is

16   indicating it's around 3.52. So variation occurs, yes, but

17   it's around 3.52. It's not going to go to 3.64.

18   Q.   And did you hear Dr. Kirsch opine that you would take

19   that .1 variability and then you could apply that to the top

20   of any of the pH values that you obtain here? Do you agree

21   with that?

22   A.   No. As I mentioned, pH 3.47, pH 3.5, already

23   variable, but it's there. You cannot input the variability

24   and assume they occur again on top of it. What that means

25   is that actual variability is .2, so up and down, above

Park - direct

1   3.52.

2   So he can -- he cannot apply .1 variation

3   already occur on top of the top value again. That data just

4   does not show that.

5   Let me, let me talk about batch 7. If you look

6   at batch 7, data point of 6 months, 3.55. 18 months, 3.46.

7   Variation is 0.09. Variation occurs around 3.50. You

8   cannot say that another .1 variation on top of 3.5. That is

9   pure speculation. Data just does not support that.

10   Q.   If there were vials of product that were in the 3.7 to

11   3.9 range, would you expect to see higher pH values in any

12   of the stability testing that has been done?

13   A.   No. Again, can you go back to showing all the values

14   from batch 1?

15   Q.   Can we get DDX-7-2?

16   A.   Right. If that's the case, we should see the pH

17   readings like in batch 1 or before manufacturing changes.

18   You can see the values are between 3.4 and 3.6, but the

19   value for 3.4 to 3.7. Right? That is the kind of variation

20   we will see. But after manufacturing changes, the data just

21   does not show such a big change.

22   Q.   So you're saying after Eagle has made the optimized

23   manufacturing changes, you are not seeing that same type of

24   variability?

25   A.   Right. Here, before manufacturing, the variation up

Park - direct

1   to 03.1, but after manufacturing, change the maximum

2   variation of 03.1, which occurs around 3.5.

3   Q.   Can we go back to the slide 36. Here on slide 36, we

4   have another section of 331 at page 26.

5   And what were the pH results again for the

6   optimization/confirmation batches 7, 8 and 9?

7   A.   Well, this is the data we have seen and Eagle,

8   according to the FDA, exactly what we have discussed. There

9   were release pH results for the confirmation batches were

10   3.50 for seven. 3.52 for batch 8 and 3.48 for batch 9. The

11   batches met the target midpoint of the pH specification as

12   designed.

13   We have seen the data, all the data we have gone

14   through varies around 3.50.

15   Q.   All right. So now based on all the data you've seen

16   in the optimized process, in your opinion, would Eagle's

17   product fall into the claimed range?

18   A.   Again, based on the manufacturing changes, based on

19   the data, we can only rely on data. Based on the data, I'm

20   confident that Eagle's proposed product would not have pH

21   outside of 3.4 to 3.6.

22   Q.   All right. And we heard some testimony yesterday from

23   Dr. Kirsch that Eagle will be unable to maintain a pH

24   specification, that the optimization process isn't working.

25   Do you agree with that?

Park - direct

1   A.   I heard that.

2   Q.   Do you agree with that?

3   A.   No. I don't agree.

4   Q.   And here on slide 38, we have DTX-800 at page 2. What

5   is being shown here?

6   A.   Well, this is the one that Dr. Kirsch has been talking

7   about and also we went through this chart.

8   Now, the left column, blue highlight, is the one

9   that was measured on November 30th. Now, pH beginning,

10   middle and ends of the sample collection was 3.54, 3.56 and

11   3.57, average 3.56.

12   First of all, these values are very close to

13   each other, so measurement is precise. Two days later, the

14   measurements were 3.51, 3.49, 3.47. Again, values are close

15   enough, very precise.

16   So because of the same samples, they pulled the

17   six values and averaged 3.52. That was reported.

18   So Dr. Kirsch is saying 3.47 and 3.57, there's

19   .1 variation. Yes, he did. That's the data. But the

20   problem here is that you cannot add a .1 value already

21   happened and to the top of the maximum value of 3.54. That

22   data just does not support it.

23   Q.   I just want to make sure I understand. So the data is

24   highlighted in blue here, 3.54, 3.56 and 3.57. Was that all

25   taken from the same set of vials?

1   A.   Right. As we discussed, when POSAs speak of stability

2   study, you collect the random samples on the same day, same

3   place, so they are the same pool of samples. You select

4   five random vials.

5   Q.   Sorry. I need to clarify my question a little bit

6   more. The beginning measurement, middle measurements and --

7   the beginning measurement, is that taken with five vials?

8   A.   Yes. Sorry.

9   Q.   The middle measurement, is that five different vials?

10   A.   Yes.

11   Q.   All right.

12   A.   I think, yes, to me as a scientist, it's so obvious,

13   but let me clarify. Beginning, you collect the sample from

14   the beginning of the process. You collect the five samples

15   and five samples collect from the middle of the filling

16   process and select the five samples from the end, so this is

17   a result of pulling five vials.

18   Q.   Okay. And then those measurements in blue were taken

19   on November 30th, you mentioned?

20   A.   Yes.

21   Q.   All right. And the measurements on the right that are

22   highlighted in yellow, 3.51, 3.49 and 2.47 were taken a few

23   days later?

24   A.   Two days later, yes.

25   Q.   By a different lab technician?

Park - direct

1   A.   Yes.

2   Q.   Were there any other PPQ batches similar to 11 that

3   were done at, that were manufactured by Eagle?

4   A.   Yes. As we move on, there are more batches. Batch

5   11, 12, 13, 14, 15, 16 and 17.

6   Q.   Those are all shown here on slide 39, which we have

7   excerpts from DDX-2-39?

8   A.   Yes.

9   Q.   I just want to ask you a couple questions based on

10   Dr. Kirsch's testimony yesterday. Dr. Kirsch was asked

11   whether in his opinion batches 1 and 13 are the same. Do

12   you believe batches 1 and 13 are the same?

13   A.   I'm not sure how batch 1 is the same as batch 13.

14   Q.   And how do you think they're different?

15   A.   Batch 1 was prepared before manufacturing changes and

16   batch 13 was made after manufacturing changes. Once again,

17   as I mentioned a few times, batch 1 still represents certain

18   properties of the final product, but not pH. Batch 13 was

19   after manufacturing process changes, so batch 1 is not the

20   same as batch 13.

21   Q.   All right. Let's turn to your final opinion on

22   inducement and what do you understand -- can you explain why

23   you believe Eagle does not directly infringe the '209 and

24   '785 patents?

25   A.   I was about to do -- Eagle will have pH around 3.4 to

Park - direct

1   3.6, will not -- I don't expect it will go to 3.7 to 3.9, so

2   it will not infringe the '785 patent.

3   It will not infringe the '209 patent, because

4   Eagle will not itself performed the claimed method of the

5   treatment, treating patients.

6   Q.   All right. And on slide 42, we have an excerpt from

7   DTX-133 at page 21. What is this document?

8   A.   Again, this is ensuring to the FDA that Eagle has

9   implemented the new manufacturing process to ensure the pH

10   remains within the established range during finished product

11   manufacturing and through the proposed shelf life.

12   Q.   And in your opinion, has this goal, has this worked?

13   A.   Yes. I can only rely on data. As you can see, data

14   shows that pH remains within 3.4 and 3.6.

15   Q.   All right. On slide 43 we have a call-up from

16   DTX-341 from page 34 from Eagle's ANDA. And what are they

17   stating here to the FDA about the optimized process?

18   A.   Again, the top highlighted portion indicates that

19   what, the target was meeting pH to middle of the

20   specification, which is 3.50, and bottom confirmed that

21   these steps were implemented to provide greater assurance

22   all future Vasopressin injection batches will remain within

23   the proposed stability specifications through the end of

24   shelf life, 24 months, for all labeled storage conditions.

25   Q.   And taking a look again at the plot of the

1   post-optimization data, what does this demonstrate to you

2   with respect to whether or not Eagle's products will remain

3   within specification?

4   A.   Now, the top shows that all the pH values are within

5   3.4 and 3.6. In particular, around 3.50 up to 18 months.

6   Bottom shows that the pH values stored at room temperature

7   up to 12 months and you can see in the beginning, pH is

8   around 3.50.

9   You can see a trend, the pH going down below

10   3.50, but above 3.40. So the data indicates to me that it

11   is very likely that Eagle's product will maintain its pH

12   between 3.4 to 3.6 throughout its shelf life.

13   Q.   So then in your opinion, would Eagle's proposed

14   commercial products infringe the asserted claims?

15   A.   No. It doesn't go to the claimed pH range of 3.7 to

16   3.9, so I don't think it will infringe the claims.

17   MS. WACKER: Your Honor, that's the end of

18   noninfringement. I have some questions for Dr. Park on

19   invalidity. I'm going to move on to invalidity. I don't

20   know if you want to pause here.

21   THE COURT: Did you figure out how you want to

22   do cross? Do you want to do it in cross?

23   MR. BLACK: No. I think we need to do it

24   altogether. Maybe this would be a good time for a break.

25   THE COURT: You said very likely that it will

Park - direct

1   remain, the range will remain between 3.4 and 3.6. That was

2   your testimony?

3   THE WITNESS: Yes.

4   THE COURT: What's very likely?

5   THE WITNESS: I cannot put any number, Your

6   Honor, but data would indicate to me all the data, pH

7   measurement between 3.4 and 3.6, around 3.5. So it did not

8   happen. I think it's not likely to happen again.

9   THE COURT: So it is very likely that it will

10   remain. Better than a 50 percent chance it's going to

11   remain between 3.4 to 3.6?

12   THE WITNESS: Personally, I think it's more than

13   that. Fifty percent is yes or no, either way.

14   THE COURT: Yes.

15   THE WITNESS: So very likely it didn't happen.

16   For example --

17   THE COURT: You think it's greater than

18   50 percent?

19   THE WITNESS: Much greater.

20   THE COURT: Much greater. Okay. All right.

21   Do you want to take a break? Would you like a

22   break?

23   THE WITNESS: I'm fine, Your Honor, if you are

24   okay.

25   THE COURT: I'm okay.

1   MR. BLACK: I'd like to have a short break.

2   THE COURT: Mr. Black would like to have a

3   break. We're going to have a break. Let's try to make it

4   short, you know. Let's try to be back at 10:00. You may

5   step down.

6   THE WITNESS: Thank you.

7   (Short recess taken.)

8   - - -

9   (Proceedings resumed after the short recess.)

10   THE COURT: All right. Please be seated. All

11   right.

12   MS. WACKER: May I get DDX-7-0? I forgot one

13   question on infringement. I apologize.

14   BY MS. WACKER:

15   Q.   You heard Dr. Kirsch testify yesterday that the PhD of

16   SVA1 could have risen from anywhere between 18 months and

17   24 months.

18   Is there any 21-month refrigeration data

19   available for that batch?

20   A.   No.

21   Q.   On the stability study, on the bridging study, is

22   there 21 month data eligible for SVA1?

23   A.   Bridging study, yes. 21 months.

24   Q.   And what is the ph measurement there?

25   A.   3.47 and 3.45, 3.49, 3.45, 3.44.

Park - direct

1   Q.   What is the 21-month stability measurement of the

2   refrigerated bridging study for SVA1?

3   A.   3.6.

4   Q.   All right. Going back to the slide, did you consider

5   the claims from the perspective of a person of ordinary

6   skill in the art?

7   A.   Yes, I did.

8   Q.   And what definition did you apply?

9   A.   A person of ordinary skill in the art is someone who

10   has a master's degrees or a pH degree in pharmaceutical

11   sciences or related skill with several years of experience

12   in developing pharmaceutical dosage forms, including stable

13   aqueous peptide formulations and more experience may

14   substitute for lower level of education and vice-versa.

15   Also, a person can have access to and

16   collaboration with persons having drug formulation

17   experience as well as pharmacologists, chemists, biologists

18   or clinicians basically can work as a team.

19   Q.   And did you consider the definition of a POSA that Dr.

20   Kirsch applied?

21   A.   Yes.

22   Q.   Would applying his definition change any of your

23   opinions in this case?

24   A.   Practically, it was not that different, so I don't

25   expect so.

Park - direct

1   Q.   And what priority date did you apply to the

2   patents-in-suit?

3   A.   February 7, 2017.

4   Q.   These dates are not disputed; is that right?

5   A.   No.

6   Q.   And what asserted claims did you consider for Eagle

7   and Amneal for purposes of invalidity?

8   A.   For the '209 patent, 1, 4, 5, 7, and against Amneal,

9   1, 2, 4, 5, 6, 7, 8. For the '785 patent against Eagle,

10   both Eagle and Amneal, claims 1, 5 and 8.

11   Q.   And are you relying on any other expert with respect

12   to any of the limitations in the asserted patents?

13   A.   Yes. For the method of treatment, I rely on Dr.

14   Cross.

15   Q.   Now, both of these, all of the claims have a

16   requirement of a pH of 3.7 to 3.9. How would you understand

17   Dr. Kirsch and Par to be reading when that pH limitation is

18   met?

19   A.   Dr. Kirsch and Par said that if claimed pH will occur

20   any time during shelf life, even for a few minutes, and that

21   will infringe the claimed pH.

22   Q.   So for a product under that definition, would a

23   product that has a pH of 3.63 for its entire shelf life that

24   rises to 3.65 for five minutes, would that infringe this

25   claim under their reading?

1   A.   Yes.   That's what Dr. Kirsch and Par interpreted and

2   that's why they rely on batch 1, which has a pH

3   out-of-specification at the end of 24 months.

4   Q.   And now have you applied that broad construction of

5   this limitation in, that broad interpretation in an

6   analysis -- sorry. Let me start over.

7   Have you applied that broad interpretation in

8   analyzing the prior art in this case?

9   A.   Yes.   In my analysis, although I don't agree with that

10   interpretation, I applied their interpretation.

11   Q.   All right. And what limitations are added by the

12   dependent claims in this case?

13   A.   Dependent claims are about the impurity levels and

14   each dependent claim is related to a specific impurity.

15   Q.   So let's talk a little bit about Vasopressin and its

16   history. On slide 51 here on the left-hand side we have an

17   excerpt from DTX-38 at page 5. What do you understand that

18   document is?

19   A.   This is a document that JHP submitted to FDA in 2010

20   as a pre-NDA letter.

21   Q.   And JHP, how are they affiliated with Par?

22   A.   JHP was purchased by Par as I recall in 2014.

23   Q.   Okay. And what did Par and JHP tell the FDA in this

24   submission?

25   A.   They indicated numerous times that they are making

1   Pitressin formulations, which was -- I can just read the

2   letter. It's probably clearer. Pitressin currently

3   marketed by JHP is the same product as the Pitressin drug

4   product previously marketed by Parke-Davis since pre-1938.

5   Q.   Okay. And on the right-hand side, this is a section

6   from DTX-25 at pages 9 through 10. What do you understand

7   that document to be?

8   A.   This is another letter to the FDA I think submitted in

9   2011, and to describe the same information, especially it is

10   a pre-1938 drug as the grandfathered product manufactured

11   and marketed by various companies without the approval of

12   FDA.

13   Q.   Does it indicate some of the companies that were

14   marketing Vasopressin products?

15   A.   Yes, because it was sold without approval, that NDA,

16   numerous companies sold, and this letter, they describe it

17   as two, American Regent and also APP as an example.

18   Q.   Now, given that there were these unapproved products

19   on the market at the time, are you aware of whether there

20   were any standards in place for Vasopressin injection

21   products?

22   A.   Yes.

23   Q.   What standards were in place?

24   A.   Each drug product sold on the market, USP has a

25   certain monograph, so it describes information, dosage form,

Park - direct

1   identity, purity, strength, all of this information about

2   specific formulations in the monogram.

3   Q.   And what is USP?

4   A.   USP is the United States Pharmacopeia that collect all

5   of the information of each product, so USP itself does not

6   have legal authority to enforce what is described here, but

7   FDA relies on USP. So all the formulation scientists,

8   companies follow USP guidelines.

9   Q.   All right. So here on slide 52, we have an excerpt

10   from DTX-135 at page 3 to 4. This is the USP from 2009?

11   A.   Yes.

12   Q.   What does it provide with respect to the pH for

13   Vasopressin injection products?

14   A.   Here it indicates that pH between 2.5 and 4.5.

15   Q.   So where does the USP get this information from?

16   A.   Usually USP get this information to make a monograph

17   from the company, usually. It may not be always. Usually,

18   they get the information from the largest manufacturer of

19   their particular product at the time.

20   Q.   So what would a POSA understand by the -- about the

21   Vasopressin injection products by the USP providing 2.5 and

22   4.5?

23   A.   Well, USP simply means that it indicates that if pH is

24   maintained between 2.5 and 4.5, the product should be good

25   for the shelf life.

Park - direct

1   THE COURT: Ms. Wacker, can you repeat your

2   question and can you slow down a little bit? I think both

3   the court reporter and I are having a hard time keeping up.

4   MS. WACKER: I'm sorry.

5   THE COURT: That's all right. I know we have an

6   answer, but I think just so the record is clear, it might be

7   good. Would a POSA understand what?

8   MS. WACKER: I will rephrase.

9   THE COURT: You don't have to rephrase. You

10   might want to actually ideally repeat what you said, but

11   slower, so we can make sure we got it.

12   BY MS. WACKER:

13   Q.   What would a POSA understand by the USP providing the

14   pH range of 2.5 to 4.5 for a Vasopressin injection product?

15   A.   Whenever a POSA makes a formulation, they rely on

16   information like a USP monograph, so it describes

17   information. Monograph describes identity, purity, purity

18   level, how to measure pH, what is pH range, all the things I

19   mentioned.

20   So a USP monograph indicates pH between 2.5 and

21   4.5, then a POSA would understand if pH is maintained

22   between 2.5 and 4.5, the formation must be good enough

23   during the shelf life.

24   Q.   Now, was there any information available regarding the

25   Pitressin product that was on the market that was unapproved

1   by the FDA?

2   A.   Information, yes.

3   Q.   And here on the left-hand side, PTX-178 at page 2,

4   what does the Pitressin label discuss about Vasopressin

5   injection products?

6   A.   Well, this is a Pitressin formulation label. It

7   indicates, as you can see on the right side, the left side,

8   it shows that how pH, pH -- how the Pitressin, that it's

9   standardized to contain 20 USP units per ml. And the

10   solution contains .5 percent chlorobutanol as a preservative

11   and the acidity of the solution is adjust with acetic acid.

12   Q.   And is that the same, are those the same ingredients

13   that are in original Vasostrict and Eagle's product?

14   A.   Yes. Exactly same.

15   Q.   And on the right-hand side, we have an excerpt from

16   PTX-145 at page 302. What information does this provide

17   with respect to the pH of the earlier Pitressin product?

18   A.   Well, you can see the third from the top, acetic acid,

19   pH adjustment, QS to pH 3.4 to 3.6 and currently marketed

20   unapproved formulation, QS to pH 3.6.

21   Q.   What does QS to 3.6 mean?

22   A.   As we have gone through QS, it means quantity

23   sufficient. In this case, add a sufficient quantity to make

24   a pH between 3.4 to 3.6.

25   Q.   That's the adjustment step where the pH is added to

1   the tank of liquid?

2   A.   Yes.

3   Q.   All right. Let's talk about your opinion with respect

4   to original Vasostrict. What are you considering as the

5   original Vasostrict prior art?

6   A.   Oh, original Vasostrict is the product that was sold

7   with a label and Eagle is making a copy of that particular

8   product as a reference drug.

9   Q.   And as of the priority date, what would a POSA in the

10 art have looked to when determining what formulation of the

11 Vasopressin injection product to make?

12 A.   There's only one FDA approved product. That's

13 original Vasostrict. So Eagle is making a copy of the

14 approved drug, so naturally, you are looking to original

15 Vasostrict.

16 Q.   Were there any differences between the Pitressin

17 product that was on the market prior to original Vasostrict

18 product?

19 A.   They are all the same except one minor difference. I

20 think that JHP applied to the mixture Pitressin formulation,

21 they're going to have an NDA approval, but then FDA, as I

22 recall, said that why don't you remove the overage and have

23 the same formulation. So Pitressin formulation then,

24 original Vasostrict, almost the same formulation.

25 Q.   And here on slide 55 we have an excerpt from DTX-26 at

Park - direct

1   page 3. What is this document?

2   A.   It's a document subject to the -- document to the FDA.

3   Q.   What is Par telling FDA about the Pitressin product?

4   A.   Again, Par, as we discussed before, they keep citing

5   the fact that the Pitressin formulation was sold before,

6   almost hundred years, indicating they are safe and

7   effective. And the bottom they show that three, there is

8   no -- sorry. So basically, they are saying that Pitressin

9   product will be the original Vasostrict.

10   Q.   Except for without overages?

11   A.   Yes. As I mentioned, FDA recommends to remove the

12   overage, so that's the only difference.

13   Q.   And what are overages?

14   A.   Before NDA application, the Pitressin formulations had

15   seven percent additional Vasopressin, so that is called

16   overage.

17   Q.   And you also, at the bottom of this section, it

18   discusses NDA registration batches. Are those the batches

19   that Par relied on to support its NDA for the original

20   Vasostrict product?

21   A.   Yes. Again, by definition, registration batches are

22   one they rely on for the product.

23   Q.   And do you understand when original Vasostrict was

24   first sold?

25   A.   According to sales records, it will be November 2014.

1   Q.   And these sales records are in DTX-86, page 1 here on

2   slide 56?

3   A.   Yes.

4   Q.   Is original Vasostrict still sold today?

5   A.   No. Par withdrew it from the market and they started

6   selling so-called reformulated Vasostrict.

7   Q.   Let's take a look at the claims of the patents and on

8   the left-hand side here, we have DTX-132. This is the --

9   actually, can you tell us what DTX-132 is?

10   A.   This is a March 2015 Vasostrict label.

11   Q.   All right. Is this the label that was sold with the

12   product when original Vasostrict was being sold?

13   A.   Yes. The label, it's coming with the product.

14   Q.   Okay. And I believe you stated you're relying on Dr.

15   Cross with respect to these limitations of the claim?

16   A.   Yes. Although as I can read it, that the indication

17   is to increase blood pressure, but I still rely on Dr.

18   Cross, because he's a medical doctor.

19   Q.   And how does the formulation of the original

20   Vasostrict product as described in the March 2015 Vasostrict

21   label, DTX-132.5, compare to the formulation requirements in

22   the '209 patent?

23   A.   I think the label made it clear that one ml solution

24   contains Vasopressin, 20 units per ml and pH was 3.4 to 3.6.

25   Now, 20 units per ml can be converted to milligram per ml

 1   concentration, because at bottom of the label it said one

 2   milligram is equivalent to 530 units.

 3   So 20 units per ml is equal to .0377-milligram

 4   per ml, which is within the range of .01 to .07 milligrams

 5   per ml in the patent.

 6   Q.   Now, in looking at the impurity limitation from the

 7   claims, how did you assess those limitations?

 8   A.   Now, limitation is the sequence homology of SEQ ID

 9   number one, which we heard yesterday is Vasopressin itself.

10   So total level in the claims said that impurities, it

11   combined it.

12   Q.   And what about for the dependent claim limitations?

13   How do you assess those?

14   A.   Right. Each dependent claim is identified by SEQ ID

15   number and also it comes with another name, Gly9, et cetera,

16   that Dr. Kirsch explained yesterday. So those individual

17   claims indicated and that's why we can calculate it.

18   Q.   Going back to the independent claim, what does

19   sequence homology mean?

20   A.   Again, SEQ ID Number 1 is Vasopressin. As Vasopressin

21   undergoes degradation or chemical changes, some portion may

22   change, but the whole structure remains similar. That's

23   sequence homology.

24   Q.   Now, in calculating the impurities of the prior

25   art, did you include unidentified impurities in the total

Park - direct

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 1    value?

 2    A.     No.    Unidentified is not identified in the individual

 3    claims, so we do not count it.

 4              MS. WACKER:  I believe we're going to have a

 5    dispute.

 6              MR. BLACK:  Your Honor, with respect to the

 7    original Vasostrict lot and the slide to follow, there's

 8    almost no disclosure in his reports, which I think we have

 9    seven.

10              This lot was manufactured after reformulated

11    Vasostrict had been on the market.  The data relating to the

12    product was provided during discovery.  They have this

13    document during the discovery period.  Amneal, there was no

14    question about whether it was sold.  It was manufactured

15    after the product had already been on the market.

16              THE COURT:  There's no question that it was

17    sold?

18              MR. BLACK:  Yes, it was sold.

19              THE COURT:  Yes.

20              MR. BLACK:  They were aware that it was sold

21    because the dates of the manufacture are on the slide.  In

22    the Amneal case, Amneal asked for sales data from 2015

23    forward and we gave it to them, and then when the cases were

24    consolidated, Eagle said, well, we want to rely on that now

25    that we know for sure it was sold, and rather than bring the
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Park - direct

1   matter to the Court, we said, fine, it's going to be in the

2   case anyway.

3   But he then gave a report with his opinion, as

4   is required, and the report mentioned this lot number, but

5   there's no data relating to the lot number in the report.

6   None of these things which are highlighted here, calculation

7   of the homologous impurities, any of this stuff is in the

8   report and we were shocked and surprised to receive a, to

9   see it in opening and in his expert testimony here today.

10   There's a second lot, the same situation, 788436

11 that they had knowledge about, was on the same list, and it

12 was sold after the -- after reformulated had been launched,

13 and we said if you want to adopt Dr. -- he had no opinions

14 on it.

15   And we said, if you want to adopt -- he had no

16 opinions on it. We said if you want to adopt Dr. Winter's

17 opinion to move the trial along, we'll let you do that,

18 and he gave us a report, which I thought was a very

19 reasonable compromise rather than bringing the matter to the

20 Court.

21   And the bottom line is that we're being repaid

22 for our largess here with clearly out-of-scope testimony,

23 which they refused to back off on this lot 788435.

24   It is not in his report and we are surprised by

25 this. They've had this for a long time. And this is really

Park - direct

1   a situation where we're being sandbagged, and I would ask

2   that they show where in the report the information that is

3   on the next slide.

4   THE COURT: Okay.

5   MS. WACKER: Okay. Can I get paragraph 8 of

6   Dr. Park's opinion report.

7   THE COURT: Actually, do I have the report?

8   MS. WACKER: I think so. There are quite a few

9   in the binder. You don't, Your Honor. I apologize.

10   THE COURT: That's all right. You don't have to

11   apologize. And I only need the one -- well, I will just

12   take what you give me.

13   All right. So where are we?

14   MS. WACKER: Paragraph 8.

15   THE COURT: Which tab?

16   MS. WACKER: It is the February 2nd, 2021,

17   report.

18   THE COURT: On, February 2nd, 2021?

19   MS. WACKER: Correct.

20   THE COURT: Okay. I'm looking at it.

21   MS. WACKER: And so just for some context, in

22   Dr. Park's opening report, he provided an opinion that

23   batches, original Vasostrict that were the representative

24   batches demonstrated the impurity profile, and we did not

25   have the sales information for this batch for the 788435,

Park - direct

1   the one that was on the slide. We didn't have the fact that

2   it was sold.

3   We learned that there were additional sales

4   records that were not produced to us in our case when we

5   were consolidated with Amneal. We learned about this as we

6   were getting ready for trial. It was a few days before we

7   were supposed to start trial in January.

8   THE COURT: Had you asked for the sales records?

9   MS. WACKER: We did. We had some of them but

10   not all of them.

11   MR. BLACK: They had not asked for sales records

12   for this time period because this is after the product had

13   been launched and therefore everybody understood that if

14   they launched. They missed this issue.

15   THE COURT: You've got to --

16   MS. WACKER: We asked --

17   THE COURT: Hold up. Sorry. The

18   significance -- you said they had not asked for sales

19   records because this is after the product had been launched.

20   MR. BLACK: They had all of the technical

21   information, and the document that's on the screen during

22   discovery, that has information about the stability data for

23   that lot. So they had all of the information, all the pH

24   information and everything they needed to run the case, but

25   they didn't rely on it.

1   They claim that they didn't rely on it because

2   they didn't know it had been sold, but all of the data on

3   that document is after the launch date and they never asked

4   us.   They didn't ask us for sales data specifically from

5   2015 forward because they knew it.   But whether they knew it

6   or not, they never gave us a report.

7   THE COURT: We'll get to that.

8   MS. WACKER: We did ask for all the sales

9   records.   I thought we resolved the issue.   Dr. Kirsch's

10   opinion, he's taking the position you have to establish

11   impurities in pH are met at the time of sale and use, so at

12   the time.

13   So when something is sold is important, and so

14   we didn't know when these batches were sold or what was

15   going on with them.   We didn't even know if they had been

16   sold because some batches are tested for stability.

17   So we got that information.   We agreed, the

18   parties agreed we could put it in a report, and he

19   specifically in this paragraph 8 talks about the lot 788435

20   and says, I understand that these lots were on sale and in

21   use before the patents-in-suit, and therefore are prior art

22   reflective of the commercial original Vasostrict product and

23   supported his earlier opinion.

24   And Dr. Kirsch after this submitted a response

25   to the opinion analyzing the data for these batches.   So

Park - direct

1   there's no prejudice here. They've actually responded to

2   it.

3   MR. BLACK: There is severe prejudice because

4   that --

5   THE COURT: Just hold on a second. So let me

6   just step back. You were just discussing homogeneity?

7   MS. WACKER: Yes. We want to talk about how the

8   impurity limitation in this batch was compared to the

9   claims.

10   And --

11   THE COURT: Hold on. So you want to talk about

12   the impurity limitation.

13   MS. WACKER: So the stability data, and if it's

14   helpful to go back to the slide, what's provided in the

15   document, DTX-360, is the actual, like, stability

16   information and pH information, and so we're showing --

17   THE COURT: Right. I get the pH. I just want

18   to make sure I understand it, because as I read the

19   paragraph in the report, paragraph 8, and I think to read it

20   in context, I have to read paragraph 7. Maybe not, but I

21   thought I did and have to then refer to paragraph 53, which

22   was the original reply report. It's all in the same

23   context?

24   MS. WACKER: In his opening report, he talks

25   about batches of Vasostrict. Although the impurity

Park - direct

1   limitations are not contested for infringement, we have to

2   establish it for invalidity.

3   So in his opening report he walked through how

4   the prior art would have established the impurity

5   limitations and what those levels are and how he calculated

6   them and not including any identified impurities, et cetera.

7   And so what he has done here is used that same

8   analysis with respect to a batch --

9   THE COURT: Should we excuse the witness?

10   MR. BLACK: Yes, Your Honor.

11   THE COURT: Sir, can you please step outside of

12   the courtroom? I apologize.

13   (Witness excused.)

14   MS. WACKER: I can get --

15   THE COURT: Hold on. He has not left yet.

16   MS. WACKER: Sorry.

17   THE COURT: Okay.

18   MS. WACKER: And then Dr. Kirsch responded --

19   THE COURT: Again, let me just step back.

20   MS. WACKER: Okay.

21   THE COURT: You all know this very, very well.

22   I don't. I can't even read the chart.

23   So we've got impurity limitations and we've got

24   pH limitations?

25   MS. WACKER: Correct.

1   THE COURT: All right. In paragraph 8 -- so

2   if you read paragraph 8 in isolation, it references the

3   data.

4   MS. WACKER: Stability data includes pH

5   information. Stability and impurity.

6   THE COURT: I've got to go slow. I'm sorry.

7   References the data, and he said that the sales

8   records confirm that a number of lots of original Vasostrict

9   for which I had cited stability testing in my reply report

10   were, in fact, sold before the priority date.

11   And then he has this very broad sentence, I

12   understand that these lots were on sale and in use before

13   the patent-in-suit, and therefore are prior art, reflective

14   of the commercial original Vasostrict product.

15   Now, I mean that's a very broad general

16   statement. It doesn't say in what respect they're

17   reflective.

18   Now, in the paragraph before it he's talking

19   about looking at the original Vasostrict product and he --

20   essentially, I think what he's focusing on is that the data

21   about the original Vasostrict, which would undermine the

22   argument that the pH range was critical. Right?

23   And so --

24   MS. WACKER: I think that was the conduct.

25   THE COURT: That's what I'm getting at. You

Park - direct

1   think paragraph 8 is a standalone paragraph. I don't read

2   it -- in other words, I'm not reading it as it's just

3   further qualifying or elucidating what's in paragraph 7?

4   MS. WACKER: I think that's right. He was using

5   this to describe, when I talked about --

6   THE COURT: My problem then is, okay. So if I

7   read paragraph 8 standalone, it doesn't really tell me

8   anything. It just basically says, hey, we've got the

9   additional sales value, very, very broad, and basically, I

10   consider it to be prior art. That's all it says. It

11   doesn't say anything about how it's prior art.

12   MS. WACKER: There are only two aspects of the

13   prior art of stability that are at issue in the case,

14   impurities and pH. And I think the important aspect here is

15   that Dr. Kirsch understood what he meant because Dr. Kirsch

16   had a responsive report whereas he looked at just a handful

17   of batches that were identified by Dr. Park, that we

18   received the late sales information for and looked at the

19   data himself and responded, so he understood what the

20   opinion was.

21   THE COURT: Show me where Dr. Kirsch said that.

22   MS. WACKER: This is Dr. Kirsch's March 23rd,

23   2021 report, paragraph 7. Do we have copies of that?

24   THE COURT: I've got Kirsch's report.

25   MS. WACKER: It's the March 23rd, 2021. And so

1   here he's talking about the specific lots, talking about the

2   stability tests and he says that --

3   THE COURT: Okay. Please, let me just get the

4   document first. So what paragraph?

5   MS. WACKER: Seven, paragraph 7. The March

6   23rd, 2021 report.

7   THE COURT: Okay. Hold on. Let me read it.

8   All right. Now, so this is kind of funny. It

9   looks like Dr. Kirsch read paragraph 8 the way I read

10   paragraph 8, because what Dr. Kirsch says is in his

11   February 2021 report, Dr. Park newly identified original

12   Vasostrict lots, blah, blah, blah, blah.

13   Dr. Park alleges that he cited stability testing

14   for these lots in his reply report "in the context of

15   challenging the criticality of the claimed pH range," and

16   that's how I read it.

17   MR. BLACK: Your Honor --

18   MS. WACKER: It's explained in his reply report.

19   Now he's saying --

20   THE COURT: What do you mean, now?

21   MS. WACKER: In his --

22   THE COURT: Right now?

23   MS. WACKER: Sorry.

24   THE COURT: The only reason we're only looking

25   at Dr. Kirsch's report is because you said that Dr. Kirsch

1   basically inferred from paragraph 8 what you're alleging

2   paragraph 8 disclosed.

3   And I asked you, I said, I read paragraph 8.

4   All you're basically saying is that very, very broad, hey,

5   we got this new data and it's reflective of prior art,

6   period. It doesn't say anything else. Right?

7   And so you say, oh, no, no, no, no, no. This is

8   a disclosure about stability testing and arguments you're

9   making about stability testing. And I specifically said,

10   okay. It looked to me maybe, maybe you've got an argument

11   about it could be used to rebut a claim that the pH range

12   was critical, the new pH range, maybe, because I read eight

13   in the context of seven.

14   You say, no, no, no, it's broader, and you say,

15   the proof of that, look at what Dr. Kirsch said. You point

16   me to what Dr. Kirsch said. A least so far, maybe something

17   else, he interprets it the way I do. What else?

18   MS. WACKER: He keeps going. He says that

19   stability testing shows that every pH measurement for these

20   original Vasostrict lots was 3.6 or lower.

21   THE COURT: Right. A pH range.

22   MS. WACKER: Yes. And then goes on to say, if

23   Dr. Park is correct that these lots are prior art reflective

24   of the commercial original Vasostrict product, this would

25   further support my opinion that he has not established that

 1   any original Vasostrict product that was on sale or in

 2   public use before the priority date of the asserted patents

 3   satisfied the pH limitations of the asserted patent.

 4   THE COURT: We're back to pH limitation. Where

 5   are we in homogeneity? I don't see it.

 6   MS. WACKER: When stability is mentioned by

 7   Dr. Park, he does limit it to stability. He said the

 8   stability data.

 9   THE COURT: I don't think he disclosed it.

10   I'm going to sustain the objection. Now, to the extent,

11   just so we're clear, Mr. Black, if there are critical

12   limitations about pH in that document, then we've got a

13   different issue, but they have not asked any questions about

14   criticality.

15   MR. BLACK: Yes. If they want to say the pH

16   was 3.6 or lower during its shelf life, I'm fine with that.

17   THE COURT: All right. We can bring the witness

18   back in.

19   BY MS. WACKER:

20   Q.   All right. Dr. Park, on slide 62 we have DTX-1362, 8

21   to 9. Do you have an understanding as to whether Vasostrict

22   lot 788435 was ever sold?

23   A.   Yes. That sales record shows that it was sold from

24   October 2015.

25   Q.   Now, turning to pH limitation here 3.4 to 3.6 --

Park - direct

1   sorry, pH limitation 3.7 to 3.9, how does that compare to

2   the pH provided in the March 2015 Vasostrict label DTX-132?

3   THE COURT: Ms. Wacker, I'm sorry. I got you up

4   at the maximum volume. When you turn to the screen, we lose

5   you and that coupled with the speed is really hard

6   sometimes.

7   BY MS. WACKER:

8   Q.   So, Dr. Park, how does the pH limitation of 3.7 to 3.9

9   compare to the pH provided in DTX-132, March 2015 Vasostrict

10   label?

11   A.   Original Vasostrict label indicates that pH was

12   adjusted to a pH of 3.4 to 3.6. I'm not a lawyer, so I

13   don't know the details about how it works, but as I

14   understand, 3.6 is abutting arrange of 3.7 that make the

15   claims obvious. So claim range requires some criticality

16   and I understand that Dr. Chyall will address it later.

17   Q.   And now you understand that Dr. Kirsch and Par are

18   reading 3.7 to 3.9 to go down to 3.65?

19   A.   According to -- yes, 3.65 can round up to 3.7.

20   Q.   Okay. 3.4 to 3.6 would go up to 3.64?

21   A.   Yes.

22   Q.   So in your opinion, would a person of ordinary skill

23   in the art expect a difference in the stability of a

24   Vasopressin formulation that has a pH of 3.64 versus a

25   formulation of Vasopressin that has a pH of 3.65?

Park - direct

1   A.   Well, I don't think any POSA will read that change.

2   Again, as yesterday we went through, pH 3.64 and pH 3.65,

3   there's only two percent difference in hydrogen ion

4   concentration.

5   Q.   And now thinking about how Dr. Kirsch and Par are

6   reading the claims, a formulation that passes through 3.7 to

7   3.9 limitation for any period of time, would a person of

8   ordinary skill in the art expect a difference in stability

9   between a formulation that has a pH of 3.6 for its entire

10   shelf life and a formulation that has a pH of 3.6 for its

11   entire shelf life other than for five minutes where it's at

12   3.7?

13   A.   As I mentioned, even if you have 3.7 throughout shelf

14   life, the difference is only two percent. I don't see how

15   being at 3.7 for five minutes would change anything.

16   Q.   Now, did you take a look at the pH specifications that

17   were in place for original Vasostrict?

18   A.   Yes.

19   Q.   And DTX-26, at page 26 on slide 24, what were the pH

20   specifications that were in place for original Vasostrict?

21   A.   For original Vasostrict, the release specification is

22   pH 3.3 to 4.0, and the way the shelf life, and during the

23   shelf life, the specification 2.5 to 4.5.

24   Q.   So when Par was manufacturing original Vasostrict, if

25   it manufactured a batch that had a pH of 3.7, could that be

1   released?

2   A.   Of course, because it's within 3.3 and 4.0.

3   Q.   And if Par had released a batch of original Vasostrict

4   that had a pH of 3.6 and drifted into the pH range of 3.7 to

5   3.9, would that be within its shelf life stability?

6   A.   Again, yes, because it's well within 2.5 to 4.5.

7   Q.   I'm only going to talk about, and I want you to focus

8   only on the pH on this slide 65?

9   A.   Yes.

10   Q.   And so going back --

11   MR. BLACK: I want to be clear, Your Honor. I

12   object to the slide, lot 788435. It has a lot of

13   information --

14   MS. WACKER: This exhibit is in evidence.

15   THE COURT: Wait. Time out. It is in evidence?

16   MR. BLACK: The exhibit, we don't have an

17   objection to the document coming in, but we have an

18   objection to them talking about it, which was sustained, and

19   we have an objection to her showing a slide which is making

20   points which Your Honor has said are beyond the report. I

21   know it's a bench trial, but --

22   THE COURT: Okay. But just so I get it, the

23   document without the highlighting is in evidence?

24   MS. WACKER: Yes. I was going to ask him about

25   pH.

1   THE COURT: Can you put up a clean document?

2   MS. WACKER: Can I get DTX -- oh, perfect.

3   THE COURT: Now, just so I will know, see the

4   highlighting there, is that in the original?

5   MS. WACKER: No, it's not.

6   THE COURT: Okay. All right. Well, now it's on

7   anyway.

8   MS. WACKER: This is DTX-360 at page 25. This

9   is again lot 788435.

10   BY MS. WACKER:

11   Q.   And what's was the pH of this product over stability,

12   over its shelf life?

13   A.   Over 24 months, it was 3.6.

14   Q.   And would you expect that there would have been a

15   difference of impurities for this lot if it had drifted to

16   3.65?

17   MR. BLACK: Objection, Your Honor. Impurities

18   of lot 788435, that whole issue was stricken. He's allowed

19   to talk about pH but not impurities. He's trying to get it

20   in through the back door.

21   MS. WACKER: I was asking, trying to ask him if

22   he expected a different formulation if they changed the pH.

23   THE COURT: All right.

24   MS. WACKER: Anyway, I already asked the

25   question and he gave an answer.

1   THE COURT: Well, wait, wait, wait, wait. Time

2   out. You already asked the question?

3   MS. WACKER: I asked an earlier question that I

4   think covers it.

5   THE COURT: Don't you think it was in violation

6   of what my ruling was about five minutes ago?

7   MS. WACKER: Sorry.

8   THE COURT: Let's not try to back-door a

9   document into evidence that I've already said can't come in.

10   MS. WACKER: I apologize, Your Honor.

11   THE COURT: I will strike the question.

12   Let's move on and let's try to avoid doing that in the

13   future.

14   BY MS. WACKER:

15   Q.   All right. So let's turn to original Vasostrict

16   registration lot 310571. Is this one of the original NDA

17   submitted batches that Par relied on in its NDA?

18   A.   Yes, it is.

19   Q.   All right. And what were the impurities for this lot,

20   310571?

21   A.   Initial indicated .8 percent, and after three months

22   it's 1.8 percent.

23   Q.   And can we go back a slide? All right. And did you

24   look at the pH information for lot 310571?

25   A.   Yes. As you can see here, it was 3.5, but at

Park - direct

1   18 months time point, it has risen to 3.8.

2   Q.   Okay. And was that 3.8 measurement within the

3   specification for this lot?

4   A.   Yes.

5   Q.   And was Par relying on this lot in support of its NDA

6   submission?

7   A.   Yes, because it was a registration batch.

8   Q.   And was this information submitted to the FDA?

9   A.   Yes.

10   Q.   All right. Now we'll go to the next slide. Again,

11   what was the stability information for this lot 310571?

12   A.   So it start at .8 percent and rose to 1.8 percent. So

13   somewhere between time zero and three months, the level

14   going through .9 to 1.7 percent.

15   Q.   And how does that compare to the impurity limitations

16   of the asserted claims?

17   A.   The asserted claims again is .9 to 1.7 percent, and

18   anytime between time zero to three months you should have

19   the claim met.

20   Q.   And this lot would have met the pH limitations of the

21   asserted claims as Par is reading them?

22   A.   Yes, because 3.8 was at the time 18-month point, so

23   according to the interpretation Dr. Kirsch and Par had, any

24   time you reach shelf life, the pH, the claimed range even

25   for a few minutes, it infringes.

1   Q.   And how did the impurities of the registration lot

2   310571 compare to the dependent claim?

3   A.   So on the left side, there are individual impurities

4   highlighted, and we have a name, like Gly9. And the

5   limitation, as you can see on the right side, claim 2 of the

6   '209 patent. For example, SEQ ID No. 2, but it also says

7   Gly9.

8   So we can go back to the left side? Gly9, look

9   at this. We can see that initial impurity .1 percent.

10 After three months, it was .5 percent. So if you go back to

11 the right side, the limitation is .1 to .3 percent. So

12 clearly, .1 percent to .3 percent is met by this lot.

13 Q.   So in your opinion, would the impurities for lot

14 310571 have satisfied the dependent claims that are asserted

15 of the '209 patent?

16 A.   Yes. If you go through, yes, it is.

17 Q.   And your opinion, impurity information for lot 310571

18 from DTX-47 at page 7?

19 A.   Yes.

20 Q.   And this is part of the NDA submission for the

21 original Vasostrict product?

22 A.   Yes. It was registration lot.

23 Q.   Now, we saw earlier that the release specification for

24 original Vasostrict was 3.3 to 4.0. Have you seen any

25 evidence that commercial lots of original Vasostrict had a

Park - direct

1   pH within the 3.7 to 3.9 range at the time of release?

2   A.   At the time of release? Yes. That's the one document

3   I was thinking about. Thank you, yes.

4   Q.   And what is DTX-1314?

5   A.   This is the lot 788436, so typical analysis.

6   Q.   And what was the pH of this lot on release?

7   A.   It was 3.7.

8   Q.   And how does that match up to the asserted claims?

9   A.   The asserted claim is pH between 3.7 and 3.9.

10   Q.   And do you know whether this lot 788436 was ever sold?

11   A.   Yes.

12   Q.   And turning to slide 72 at DTX-1362, pages 9 to 2,

13   when was this lot sold?

14   A.   You can see the sales record indicates it was sold in

15   November of 2015.

16   Q.   Let's turn to the impurity limitations. Did you look

17   at the impurity profile for 788436 and compare it to the

18   requirements of the asserted claims?

19   A.   Yes, I did.

20   Q.   Okay. And what is your opinion with respect to the

21   impurity level of lot 788436?

22   A.   Well, impurity level of lot 788436 is .7 percent:

23   1.6 percent.

24   Q.   Okay. And that the homologous impurity of 0.7, that's

25   at release?

Park - direct

1   A.   Yes.

2   Q.   Okay. And that's at -- that's below the range of .9

3   to 1.7?

4   A.   Right. We narrowed it over time, Vasopressin

5   degrades, so the impurity level increases. So from here,

6   impurity level would only increase .7 percent to .9, et

7   cetera. The difference in impurity level would depend on

8   how you store it. If you store it at refrigeration

9   temperature, it may increase slowly, more slowly than stored

10   in the room temperature.

11   Q.   All right. So in conclusion, what is your opinion

12   with respect to whether or not the independent claims of the

13   '209 and '785 patents are met by the original Vasostrict

14   product?

15   A.   Well, as we have gone through original Vasostrict

16   label had all the elements of the claim, so the Vasostrict

17   label makes the independent claims of the '209 and '785

18   patent.

19   Q.   Okay. And with respect to the pH limitation, when

20   considering the original Vasostrict product as sold, do

21   you believe that that limitation would be met by the prior

22   art?

23   A.   Yes. Again, it was 3.6, and as I mentioned, it is

24   abutting range to 3.7. I mentioned clearly I'm not a

25   lawyer, so I don't know how the intricacies of how law

Park - direct

1   works, but as I understand, 3.6 is the abutting range with

2   3.7, especially when we consider 3.64, 3.6. 3.65 to 7. The

3   difference is really minor, so I think it met the claims.

4   Q.   And what is your opinion with respect to whether or

5   not the original Vasostrict met the limitations of the

6   dependent claims?

7   A.   Again, as we have gone through one by one, original

8   Vasostrict label indicates that all the impurity claims are

9   met. So original Vasostrict renders dependent claims of the

10   '209 and '785 patents obvious, too.

11   Q.   All right. And if a POSA obtained the original

12   Vasostrict product that was sold, would they be able to

13   measure the impurity level of that product?

14   A.   If they have a sample, yes, they can measure, so

15   impurity level will be there. You can measure pH impurity

16   level from the product.

17   Q.   So a person of ordinary skill in the art would be able

18   to determine the properties of that product that was sold?

19   A.   Right. Properties with inherent value, you can

20   measure pH any time, so you can measure pH whenever there's

21   a sample available.

22   Q.   Do you understand that we're doing a little bit of

23   prebuttal, what we think Dr. Kirsch is going to say here

24   with respect to some of the teaching away evidence, but do

25   you understand that Dr. Kirsch has opined in this case that

Park - direct

1   there are certain references that teach away from the

2   claimed invention?

3   A.   Yes, I do.

4   Q.   Okay. Do you agree with him, the references teach

5   away from the claimed invention?

6   A.   No. I have not seen any, any evidence, any document

7   that indicates that it teaches away from having a

8   formulation that has a pH only for a few minutes during

9   storage.

10   Q.   And if looking at specifically PTX-145 at pages 302 to

11   303, what do you understand this document to be?

12   A.   This is the biopharmaceutics review. The FDA reviews

13   and renders a decision like this.

14   Q.   And this is an FDA review with respect to Par's

15   original Vasostrict product?

16   A.   Yes.

17   Q.   All right. And do you understand Dr. Kirsch is

18   relying on that statement at the top of slide 76 in support

19   of his argument that they're teaching away from the claimed

20   invention?

21   A.   That's what he understood, yes.

22   Q.   And would you understand this statement to be teaching

23   away from a formulation that was manufactured at a pH of 3.4

24   to 3.6 that then drifted into a pH of 3.65 for five minutes?

25   A.   I don't see any teaching like that from this

Park - direct

1   statement.

2   Q.   Why do you disagree with that opinion of Dr. Kirsch?

3   A.   Now, Dr. Kirsch may rely on this particular statement

4   here. The pH of the formulation is critical because at pH's

5   below 3.4 and above 3.6, degradation Vasopressin accelerates

6   and that's what they rely on.

7   Now, the issue always for scientists is without

8   data, how do you know, how can you predict this, especially

9   when interpretation by Dr. Kirsch and Par is that you can

10   maintain pH 3.4 to 3.6 and go to 3.7 for five minutes, it

11   still infringe.

12   Now, in that case, we want to know if pH goes to

13   3.7 for five minutes, how does it accelerate degradation?

14   This is why scientists need to see the data. Without data,

15   anything that you say is speculation. That's why we always

16   rely on data. So I don't see any data here.

17   So, first of all, I think the statement is

18   rather vague and uncertain, especially in relation to Dr.

19   Kirsch and Par's interpretation of the infringement.

20   Q.   Have you seen any information regarding the pH

21   limitations for -- that were in the prior art before the

22   priority date?

23   A.   I'm sorry. Your question again?

24   Q.   Have you seen any information with respect to the pH

25   of, disclosed for Vasopressin injection formulation in the

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1   prior art?

2   A.   Oh, of the formulation? Yes.

3   Q.   And on slide 77, at the top here, DTX-135, this is the

4   USP that we looked at earlier?

5   A.   Yes. The monograph information.

6   Q.   And what pH value does the USP provide?

7   A.   Again, it's 2.5 to 4.5, which includes 3.7 and 3.9.

8   Q.   And on the top right, DTX-144 at page 3, what is

9   DTX-144?

10   A.   This is a Lithuanian patent. A patent clearly

11   indicates that pH is tested and its value must be in the

12   range of 3.8 to 3.95. So clearly that range was already

13   known.

14   Q.   And then the Pitressin product that we discussed,

15   DTX-188 at page 6, what was the pH of some of the -- of the

16   Pitressin that was available in the prior art?

17   A.   Well, you can see the beginning, you start with

18   3.7 and measurements were made after three months, 3.8.

19   Six months, 3.7. Nine months, 3.7. So within the claim

20   range.

21   Q.   And we already discussed DTX-1314 at page 1 provides

22   the pH specification for original Vasostrict. Why is that

23   relevant for your analysis here?

24   A.   Why is it relevant to my analysis? This covers the

25   claimed range of 3.7 to 3.9.

1   Q.   So in view of the prior art references to pH of

2   original -- sorry.

3   THE COURT: Is there an objection? Hold up. Go

4   ahead.

5   MS. WACKER: Oh.

6   MR. BLACK: I will let her finish the question.

7   THE COURT: I thought you objected to something

8   else.

9   MR. BLACK: No.   I'm objecting.   She's calling

10   these prior art, but they are not prior art.   The first two

11   documents were published, they are prior art.   The bottom

12   two documents are internal Par documents that are not prior

13   art, so to call them prior art --

14   BY MS. WACKER:

15   Q.   Dr. Park, do you understand that Pitressin was being

16   sold before the priority date of this patent?

17   A.   That is what sales records indicate.

18   Q.   All right.

19   A.   It was sold before the priority date.

20   MS. WACKER: Can I get DTX-638 up on the screen,

21   page 1.

22   BY MS. WACKER:

23   Q.   And -- I forget the number now.   Oh, 78495.   When was

24   lot 78495 sold? April 18th? It was lot 78495 sold

25   April 18, 2008?

1   A.   2008, April 18th, yes.

2   Q.   Can you go back to the slide. And do you understand

3   that this lot of original Vasostrict 788436 that's

4   referenced here on DTX-1314 was sold?

5   A.   Yes.

6   Q.   All right. And now back to my earlier question. A

7   person of ordinary skill in the art having an understanding

8   of these pH ranges and values of the prior art, Vasopressin

9   injection product, how would that impact whether or not they

10   are taught away from the 3.7 to 3.9 range?

11   MR. BLACK: Objection, Your Honor. Not prior

12   art. The bottom two items are not prior art. They're

13   internal documents.

14   MS. WACKER: The products, the lot themselves

15   are prior art.

16   MR. BLACK: She hasn't established that the lots

17   were sold at these various pH levels or that one of ordinary

18   skill would have that information in front of them. She has

19   to ask a precise question if she wants to call them prior

20   art.

21   BY MS. WACKER:

22   Q.   Dr. Park, original Vasostrict lot 788436, we

23   established that?

24   A.   Yes.

25   Q.   It was released with a pH of 3.7?

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1   A.   Yes.

2   Q.   And a person of ordinary skill in the art, I think you

3   testified to this earlier, would be able to measure the pH

4   of that lot when it was sold, right?

5   A.   Again, pH is an inherent property that does not

6   change, so anybody can measure it. So once product is sold,

7   its property belongs to prior art. Again, I'm not a lawyer,

8   but that's my understanding.

9   Q.   Okay. And would that be the same for the Pitressin

10   lot, 78495?

11   A.   That's right.

12   Q.   So now you have these two lots that are available with

13   the -- that have pH's in the 3.7 to 3.9 range at some point

14   in their shelf life and the prior art on the top, how would

15   that impact whether a person of ordinary skill in the art

16   would be taught away from 3.7 to 3.9?

17   MR. BLACK: Objection. Assumes facts not in

18   evidence about 788436, that it was ever sold at a pH of

19   3.7.

20   The trouble is, if she wants to ask a question

21   about whether USP 2009, for instance, would have taught

22   something and what it would have taught to someone of skill

23   in the art, that's a published document. If she wants to

24   ask a question about an internal Par document for a lot that

25   was sold, she has to establish that somebody had that

 1   information.

 2   POSAs don't test millions of vials sold.

 3   There's one that came out at 3.7, what did that teach? We

 4   say nothing, but she has to ask a question. You can't call

 5   it prior art unless she can establish it.

 6   BY MS. WACKER:

 7   Q.   In your view --

 8   THE COURT: Hold up. What do you think? What

 9   he said sounds right to me, so what do you say?

10   MS. WACKER: I don't want to argue too much in

11   front of the witness, but this is the issue. They are

12   saying you have to establish it at the time that it was

13   sold, at the time it was administered, and what Dr. Park is

14   saying is that the information that we have, because we have

15   only what Par has been able to produce to us, right, that's

16   representative of their original Vasostrict product, that

17   the information we have demonstrates that their products and

18   the earlier Pitressin products likely had a pH over its

19   shelf life in the same range.

20   THE COURT: Let's do this. I'm sorry to ask

21   you, Doctor.

22   THE WITNESS: Yes, sir.

23   THE COURT: If you need to use the restroom, go

24   ahead.

25   THE WITNESS: Yes.

1   (Witness excused.)

2   THE COURT: All right. It seems to me, I mean,

3   I understand the objection, and so do you want to respond?

4   MS. WACKER: Yes. And so I think Dr. Park's

5   opinion is that it's the original Vasostrict product that

6   was sold as a whole, right, and so this is representative of

7   the pH and he has shown a couple of examples of the pH

8   that's representative of the original Vasostrict batches

9   that were being sold and how they had multiple instances

10   where it was released at a higher pH or rose up to a higher

11   pH.

12   THE COURT: Doesn't it have to be known to the

13   artisan of ordinary skill that when it was released, it had

14   the pH at whatever level you said?

15   MS. WACKER: Not for an on-sale bar. So for

16   a product that's actually sold, and you can consider on-sale

17   products --

18   THE COURT: Okay. You know patent doctrine.

19   I've heard of on-sale bar. I have no idea the relevance to

20   this particular issue, so you are going to have to explain

21   why.

22   MS. WACKER: Yes.

23   THE COURT: I thought that what is relevant here

24   is we're on teaching away and we're on whether or not

25   certain prior art references would teach something to an

1   artisan of ordinary skill. And Mr. Black has said, he has

2   admitted that the Pitressin that was on the market, that,

3   the fact that it's on the market and it's out there is prior

4   art, but whether or not it had certain properties that you

5   have to test for, if those test results are not public

6   information, we can't assume that that information, the test

7   result information, is prior art. That makes sense to me,

8   and I think you agree with it?

9   MS. WACKER: I don't, I don't.

10   THE COURT: Okay.

11   MS. WACKER: So when you have a product that's

12 sold, that you will be able to know the properties about,

13 because if we were back in 2016 when this product was being

14 sold, we could test it. Right? You could measure the pH,

15 you could measure the impurities.

16   So if you have evidence as to what the

17 properties of that product were, that is representative of

18 the product that was being sold and you can use that in part

19 of your obviousness defense.

20   So even though a POSA can't go back in time and

21 test it, if those are the properties of the product, that's

22 representative of what was being sold. So original

23 Vasostrict was being sold by Par. They had very broad pH

24 specifications.

25   Now they are trying to say, well, that can't

1   invalidate our patent even though you are copying it because

2   you don't have specific evidence that we sold a batch on a

3   day when it had those impurities and we're never going to

4   have that evidence because you can't go back in time and

5   take something from a hospital and measure it. So that's

6   why the law is you can see what the properties are of that

7   original product that was being sold. The same for

8   Pitressin.

9   THE COURT: Okay. Mr. Black, what do you say to

10   that?

11   MR. BLACK: I disagree that she is using -- let

12   me put it this way. When a POSA is looking at the prior

13   art, they can consider all the prior art that's available.

14   They look to documentation, they look to standards, they

15   look to the FDA that teaches away from 3.4 to 3.6.

16   They look at the documents that are out there.

17   They might also have other evidence. They might have -- but

18   they have not shown that would be so in the real world.

19   And what they certainly can't do is say that

20   because there was one lot of Pitressin that at one point in

21   its life was 3.7 before it was sold, nine months before it

22   was sold, that that is prior art, and they can't consider it

23   alone.

24   The standard for Pitressin was 3.4 to 3.6 and

25   all -- original Vasopressin. All the evidence we have,

1   there were millions of vials actually sold at 3.6. They

2   found a stray 3.7 value and are representing it as prior

3   art.

4   THE COURT: Kind of like SVA1 is a stray value

5   that has been --

6   MR. BLACK: No, Your Honor. SVA1 is reflective

7   of the fact that their product has an upward statistically

8   significant drift of the .024 pH at the time they registered

9   the product, and when I cross-examine Dr. Park, I am going

10   to show the same thing is true of their so-called

11   optimization batch.

12   This is prior art. They're trying to invalidate

13   our patent with non-public material. There are rules for

14   that. It's wrong for her to say this is the prior art, this

15   is what would have been taught. It's a misleading question.

16   There are plenty of ways to get the evidence in

17   and then argue from it, but they're arguing that someone

18   would teach away from the FDA if we ignore the FDA ruling

19   because there's one document an internal document from Par.

20   That doesn't make sense. It's also so far away to be

21   relevant, it's inadmissible. We should move on.

22   MS. WACKER: And I think what he's saying is if

23   a person of ordinary skill in the art understanding the

24   properties and their original Vasostrict and Pitressin in

25   prior art, knowing that they can go in the 3.7 to 3.9 range

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 1   would not be taught away from 3.7 to 3.9.

 2   I have a case for you, Abbott versus Sunovion

 3   Pharmaceuticals.

 4   THE COURT: Well, here's the thing. I

 5   appreciate the case. I'm going to have to study the law

 6   and make an informed decision about this.

 7   I am going to allow the question to be forward.

 8   You need to think about the risks of contaminating what

 9   otherwise might be probative and what I would admit by

10   combining all these things together. I will leave that to

11   you. That's your discretion.

12   I will overrule the objection, but I'm going to

13   study the issue, and if Mr. Black turns out to be right, and

14   I have no way of knowing until I read the case law, you may

15   have taken a great risk. But you'll have to decide how to

16   proceed.

17   All right. Let's bring the witness back in.

18   Thank you.

19   MS. WACKER: May I proceed?

20   THE COURT: Yes.

21   BY MS. WACKER:

22   Q.   All right. So, Dr. Park, just considering the top two

23   references, USP 2009 and the Lithuanian patent, having those

24   two prior art references in mind, would a person in your

25   view, would a person have been taught away from the 3.7 to

1   3.9 range?

2   A.   No.   First of all, USP monograph that all formulation

3   scientists follow clearly indicate pH between 2.5 and 4.5.

4   Also, there are patents claiming 3.8.   The only document Dr.

5   Kirsch referred to was a document with review.   As I

6   mentioned, the document statement is uncertain, vague

7   without data, especially when we interpret the infringing

8   claims that pH remains 3.4 to 3.46 for 24 months.   At the

9   end, only for five minutes goes to 3.7.

10   The question naturally occurs, how fast

11   degradation accelerates.   Does it make the whole product

12   unusable?   We don't know.   It's new information.   So

13   overall, I don't think that teaches away.   And I have not

14   seen any document that indicates it teaches away.

15   Q.   And now a person of ordinary skill in the art

16   understanding the properties of the Pitressin and original

17   Vasostrict products that were on the market in the prior

18   art, would that person of ordinary skill in the art have

19   been taught away from the 3.7 to 3.9 range?

20   A.   No.   Again, anyone can measure the pH and as we've

21   seen here, some vials have 3.7.   Yes, that's exactly what

22   it's saying.   Some vials, 3.7.   So we have seen the data,

23   product sold has a pH of 3.7.   Anybody can measure.

24   Q.   All right.   So let's turn to your opinions on

25   materiality and here we have claim 1 of the '239 patent,

Park - direct

1   PTX-605, page 33.

2   Can you describe generally what this claim is

3   directed to?

4   A.   Yes. This claim is related to a method of treatment

5   using Vasopressin formulation having a certain impurity

6   profile drug concentration and with certain pH information.

7   Q.   Okay. And in the context of the '239 patent, what

8   reference did you consider with respect to materiality?

9   A.   Oh, again, 2014 data label. It has more information.

10   Q.   Okay. That's DTX-36, pages 1 to 3?

11   A.   Yes.

12   Q.   Okay. And are you relying on Dr. Cross for any of

13   these limitations?

14   A.   Again, method of treatment is required, a medical

15   doctor's statements.

16   Q.   And so in your opinion, are you relying on Dr. Cross

17   that the April 2014 Vasostrict label, DTX-36, satisfies the

18   method of treatment limitation of claim 1 of the '239 patent

19   on slide 8?

20   A.   Again, any POSA can read the claims in the patent,

21   but, again, I'm relying on Dr. Cross for method of

22   treatment.

23   Q.   All right. Now, when looking at the April 2014

24   Vasostrict label, DTX-36, how does that compare to the

25   formulation aspect of the '239, claim 1?

1   A.   Now, this is the most interesting part.   Now, label

2   clearly indicates pH was adjusted to 3.4 to 3.6 and '239

3   patent claims pH 3.5 to 4.1, which includes 3.4 to 3.6.

4   Q.   And how about the amounts, the unit amounts?   How do

5   they compare of the April 2014 Vasostrict label?   How does

6   that compare to the limitations?

7   A.   Again, the label clearly indicates that one ml

8   solution contains Vasopressin with 20 units per ml, which we

9   went through, within 0.07 mg/ml -- the claimed range.   Also

10   it has a chlorobutanol as a preservative and water and

11   acetic acid.   So label has every single element claimed in

12   the '239 patent.

13   Q.   Now, with respect to impurities, during prosecution,

14   what did the Examiner state in the '239 patent?

15   A.   Well, the '239 patent, the claims indicate the level

16   of zero to two percent, individual impurity as claimed in

17   the claims 2, 3 and 4.

18   Now, the Patent Examiner stated that --

19   MR. BLACK: Objection, Your Honor.   Hearsay.   He

20   is going to testify about what the Patent Examiner said

21   where the issue here is whether or not the degradation

22   product limitation of the '239, zero to two percent.   We

23   have not seen that before, but it's an impurity related

24   measurement, zero to two percent degradation product.

25   THE COURT: Hold on one moment.

Park - direct

 1   MR. BLACK: Yes, I'm sorry.

 2   THE COURT: All right. So the question is with

 3   respect to impurities during prosecution, what did the

 4   Examiner state in the -- it's a hearsay objection.

 5   MR. BLACK: And relevance.

 6   THE COURT: Okay. Well, let's deal with the

 7   hearsay first. What is this being -- it's clearly, it's

 8   an out-of-court statement made by a declarant who is not on

 9   the stand. Unless you come up with an exception, it's

10   hearsay.

11   MS. WACKER: Public record is 8038. This is an

12   official prosecution history filed for a patent.

13   THE COURT: Okay.

14   MS. WACKER: And he's just reading a statement

15   from that public record.

16   THE COURT: And what is it being offered for?

17   MS. WACKER: The fact that the Examiner said

18   that the concentration --

19   THE COURT: The fact -- why is it relevant?

20   MS. WACKER: It's relevant to inequitable

21   conduct.

22   THE COURT: Go ahead.

23   MS. WACKER: All Dr. Park is doing is comparing

24   the prior art label, which is something that as you heard

25   during Mr. Hales' opening, Par submitted declarations so

1   that this label would not be considered as prior art for the

2   '239 patent and then we're having Dr. Park just walk through

3   the label and compare it to the claim.

4   MR. BLACK: My complaint is that they're relying

5   on a statement from the Examiner in the middle of

6   prosecution. Those statements often are reversed. They

7   become moot.

8   He's not qualified to talk about what the

9   Examiner said and what the Examiner said during prosecution

10   on the point, scientific point about the degradation product

11   is irrelevant.

12   If he has an opinion --

13   THE COURT: Well, wait. Hold on. Hold on.

14   MR. BLACK: I'm sorry.

15   THE COURT: So because you started saying he

16   doesn't, you're now talking about Dr. Park offering an

17   opinion or interpreting.

18   MR. BLACK: Yes.

19   THE COURT: So my first reaction is that if the

20   inequitable conduct is going to be based on assertions that

21   are made in response to what the Patent Examiner asked, then

22   the Patent Examiner's statements aren't being offered for

23   the truth of the matter. They're not hearsay and they just

24   give context and the fact that they were said.

25   Now, if they're going to ask, well, what was the

Park - direct

1   Patent Examiner thinking or anything other than what the

2   statement is and this is just a vehicle to get it read into

3   the record, then do you object?

4   MR. BLACK: Yes.

5   THE COURT: Okay.

6   MR. BLACK: I object to that because that's what

7   I think they are doing. Examiner, degradation product in

8   the April label are inherent. He's going to give his

9   opinion on whether they are inherent. That's okay. He's a

10   scientist.

11   THE COURT: Right.

12   MR. BLACK: He can't back himself up with

13   statements from the Examiner in the middle of prosecution.

14   This doesn't really provide context for the inequitable

15   conduct argument.

16   This part of the presentation is about whether

17   the label matches up with the '239 patent and he's trying to

18   use the Examiner's statement to try to give credibility to

19   that. She's not here to be cross-examined. If he wants to

20   give his opinion, that's fine.

21   MS. WACKER: And all he's doing here, he's not

22   saying it's inherent. What's relevant to materiality is

23   whether or not this reference would have been material to

24   the issue of the patent. Right? And so this label was

25   disqualified as prior art based on declarations, so he's

Park - direct

1   comparing all of the limitations. The Examiner stated she

2   believed these limitations were inherent.

3   For the '239 patent then, which satisfies all of

4   the pH, all of the other limitations, the Examiner has a

5   view that the SEQ ID numbers, the impurities, were an

6   inherent feature of the product.

7   THE COURT: All right. I'm going to allow the

8   question and I think it's appropriate to put on the record

9   what the Patent Examiner said. It is a public record, first

10 of all. More importantly, we've got an allegation of

11 inequitable conduct before the Patent Examiner, and so -- I

12 mean, let me ask you all. You're both patent lawyers.

13 Have you ever tried a case with inequitable conduct before?

14   MS. WACKER: I have not.

15   THE COURT: Mr. Hales, have you?

16   MR. HALES: I have, Your Honor, yes.

17   THE COURT: Have you defended against

18 inequitable conduct?

19   MR. HALES: Not in the one that went to trial.

20   THE COURT: But you've been in a trial where you

21 argued inequitable conduct?

22   MR. HALES: I take that back. Perhaps not. I

23 can't even remember one, but they're in some obviously and

24 I've been on both sides.

25   THE COURT: I guess what I'm getting at is, the

Park - direct

1   reason why I'm asking the question is I can't believe in

2   patent cases we call to the stand patent examiners.

3   MR. HALES: No, we're not.

4   THE COURT: In fact, my guess is there's

5   probably a bar on it, but I don't know.

6   MR. BLACK: There was a cottage industry with

7   former PTO commissioners doing expert reports, but that was

8   put to bed some years ago.

9   THE COURT: Right. And that makes sense to me

10   as a non-patent person, and if we couldn't put the Patent

11   Examiner's statement into the record, I don't know how you

12   would almost ever prove or be allowed to go forward with an

13   inequitable conduct case.

14   So I'm going to allow the Patent Examiner's

15   statements to be put in the record. I don't think they are

16   hearsay, I think they're an exception, mainly because I

17   don't think they're being asserted for the truth of the

18   matter. Even if they were, I find a public record

19   exception.

20   Now, so the statements are coming in. Now,

21   you've got another objection which is to what?

22   MR. BLACK: Well, it depends on her question.

23   THE COURT: Okay.

24   MR. BLACK: Statements coming in, I don't really

25   have a problem with that part of the part of the file

1   history being in.

2   THE COURT: That's what you objected to.

3   MR. BLACK: No. I was objecting to the

4   question, and this witness, this witness' -- I'm objecting

5   to it being offered for the truth of the matter asserted.

6   Your Honor has dealt with that. It's hearsay, but it's a

7   public record exception.

8   THE COURT: It's not hearsay because it is not

9   being offered for the truth of the matter and I'm not going

10   to accept it as the truth of the matter.

11   MR. BLACK: Okay.

12   THE COURT: It goes to the Examiner's state of

13   mind to the extent the Examiner asked something. For

14   example, if the Examiner said, I need this information

15   before I can sign off on this patent, that is admissible, it

16   seems to me, because, again --

17   MR. BLACK: Yes. That's something we can -- the

18   use of the document we can deal with. I just didn't want to

19   let the moment pass and have their inherency case be put in

20   effectively by a statement from the Examiner that was being

21   offered for the truth.

22   THE COURT: Okay. I see.

23   MR. BLACK: Dr. Park can testify.

24   THE COURT: That's a fair thing. So just --

25   MS. WACKER: And I wasn't going to ask him that

Park - direct

1   anyway.

2   THE COURT: I mean, in fairness to Mr. Black

3   here, I would be doing what he did given that the title of

4   the slide is degradation products in April 2014 Vasostrict

5   label formulation are inherent, so I understand where he's

6   coming from.

7   MS. WACKER: I understand.

8   THE COURT: All right. So, all right.

9   MS. WACKER: All right.

10   THE COURT: The objection is overruled. Let's

11   go.

12   BY MS. WACKER:

13   Q.   Dr. Park, and I don't recall if we have an answer to

14   the question. Let me re-ask it. What did the Examiner say

15   with respect to the impurity limitations in the '239 patent?

16   A.   Well, the record shows that the Examiner said a

17   concentration of SEQ ID numbers 2 and 4, which are in brief

18   here, in the formulations is an inherent feature of the

19   prior art formulation, which is original Vasostrict.

20   Q.   Okay. And now the original Vasostrict product, do you

21   know what the impurity limitations were for that product?

22   And I think we went over this before, lot 310571. We have

23   an excerpt.

24   A.   What was the question?

25   Q.   What were the impurities for that original Vasostrict

Park - direct

1   product?

2   A.   Oh, the samples stored upright position at 25 degrees

3   Centigrade. Initially, we think the level was 1.1 percent.

4   It rose to 2.4 percent at three months. So it clearly meets

5   the claim limitations of their two percent degradation

6   product.

7   Q.   So in your opinion would the April 2014 Vasostrict

8   label have been material to claim 1 of the '239 patent?

9   MR. BLACK: Objection, Your Honor. Materiality

10   is a legal question.

11   BY MS. WACKER:

12   Q.   Was the April --

13   THE COURT: Hold on. Are you withdrawing the

14   question?

15   MS. WACKER: I have withdrawn the question.

16   THE COURT: Okay. Sorry. Go ahead.

17   BY MR. WACKER:

18   Q.   And in your opinion, would the April 2014 Vasostrict

19   label have invalidated the claims of the '239 patent?

20   A.   Again, information described in 2014 Vasostrict label,

21   has all the elements claimed in the '239 patent, so I

22   believe that it invalidates the '239 patent.

23   Q.   All right. Let's turn to the '209 patent.

24   Are you relying on Dr. Cross, this is on slide

25   85 and looking again at DTX-36, pages 1 through 3. Are you

1   relying on Dr. Cross with respect to the method of treatment

2   limitations here?

3   A.   Yes. Again, I'm relying on Dr. Cross on method of

4   treatment.

5   Q.   How does the April 2014 Vasostrict label compare to

6   the formulation limitations of the '209 and '785 patents?

7   A.   Again, as we went through, the amount of Vasopressin,

8   20 units per ml, which is equivalent to .0377 milligrams per

9   ml, which is within the range claimed in the '209 and '785

10   patents.

11   Q.   And how does the pH limitation of the '209 and '785

12   patents compare to the pH described in the April 2014

13   Vasostrict label?

14   A.   Again, I went through, so I'm not going to go through

15   all answers again, but 3.6 is abutting the range to 3.7.

16   Q.   And what were the impurity levels for, again, for lot

17   310571 and how did they compare to the claim limitations?

18   And here on slide 87, we have an excerpt from DTX-45 at

19   page 7?

20   A.   Again, the samples show that upright position at

21   25 degrees Centigrade, initially .08 percent at three

22   months, 1.8 percent. So in between initial and three

23   months, the treatment level must have gone to .1 to

24   1.7 percent.

25   Q.   So in your opinion, would the April 2014 Vasostrict

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 1    label invalidated the '209 -- let me repeat that.  Was the

 2    April 2014 Vasostrict label have met all of the limitations

 3    of the '209 and '785 patent, claim 1?

 4    A.    Yes.   2014 label meets all the elements except the pH

 5    3.6, which is the abutting range.  So I think it makes the

 6    independent claim of the '209 and '785 patents obvious.

 7              MS. WACKER:  No further questions.

 8              THE COURT:  All right.  Thank you.  Mr. Black?

 9              MR. BLACK:  Take a short break, Your Honor?

10              THE COURT:  Well, we're coming up on lunch, so I

11    mean, you're going to be probably a while.  Right?

12              MR. BLACK:  I'm going to be a while, yes.

13              THE COURT:  Why don't we go.  Then we'll break

14    for lunch.  Is that all right?

15              THE WITNESS:  Yes.

16              THE COURT:  Okay.  Thank you.

17              THE WITNESS:  For the record, I'd like to spell

18    my name, K-i-n-a-m.  Kinam is a good name, too.

19              MS. WACKER:  Your Honor, I forgot to move

20    exhibits in.  Do you want me to do that later?

21              THE COURT:  Just do it later.

22              MS. WACKER:  It's a long list.

23              THE COURT:  Then especially.  Whenever you are

24    ready, Mr. Black.

25              MR. BLACK:  Thank you.
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1   **CROSS-EXAMINATION**

2   BY MR. BLACK:

3   Q.   Good morning, Dr. Park.

4   A.   Good morning.

5   Q.   You started by discussing your qualifications and you

6   are clearly an eminently qualified expert in pharmaceuticals

7   and with an expertise in peptides, and I think you would

8   agree that Dr. Kirsch is a colleague who also shares those

9   qualifications. Would you agree?

10   A.   Absolutely.

11   Q.   And Dr. Winter actually is part of the peptide club as

12   well. Right? Do you know him?

13   A.   No, I don't know him.

14   Q.   You don't know him. Okay. You do know Dr. Kirsch.

15   Dr. Shawl is not a peptide expert; is that

16   correct?

17   A.   Dr. Shawl?

18   Q.   Yes.

19   A.   I don't think so.

20   Q.   You --

21   A.   But I don't know. Just want to clarify.

22   Q.   He's not somebody who you run into at conferences,

23   like Dr. Kirsch, see publications frequently. Correct?

24   A.   I'm sorry. Dr. Kirsch? What about Dr. Kirsch again,

25   please?

Park - cross

1   Q.   You and Dr. Kirsch see each other at conferences, read

2   each other's publications from time to time; correct?

3   A.   Yes.

4   Q.   That would not be true of Dr. Shawl; correct?

5   A.   I have not met him, so, yes, that may be true.

6   Q.   Let's discuss the ANDA process a little bit. Now, the

7   ANDA holder files an application with the FDA, which is a

8   voluminous set of documents and data where they try to

9   establish sufficient similarity to an approved drug so that

10 they can sell the generic drug. Right?

11 A.   Yes. Generic product needs to show safety and

12 efficacy similar or same as the RLD.

13 Q.   And there are many variations between the generic drug

14 and the RLD that are permitted by the FDA; correct?

15 A.   Could you be more specific, what variation.

16 Q.   You put up a slide that implied that the only thing

17 that mattered were in this case the pH and a few other

18 things, but the FDA will actually permit significant

19 variation in characteristics between the generic drug and

20 the RLD; right?

21 A.   Well, I cannot answer in general. I don't know the

22 FDA regulations.

23 Q.   The impurity profile of the generic drug can be

24 significantly different from the impurity profile of the

25 RLD; right?

Park - cross

1   A.   That I don't know.

2   Q.   You don't know?

3   A.   I don't know the FDA regulation.

4   Q.   Okay. In a case like this, we only have a limited

5   amount of data available to determine what the commercial

6   product will actually be like; correct?

7   A.   I don't think that's true.

8   Q.   In a typical ANDA case, you have a few batches, some

9   data on those batches and the FDA has to make a decision

10   about whether to approve the product based on those limited

11   batches, but, of course, in the real world, there will be

12   many, many, many commercial batches; is that correct?

13   A.   In real world, there are many more commercial batches,

14   but FDA requires testing certain batches and the product,

15   can the product be represented by the stability study.

16   That's what Dr. Kirsch understood. Do you present whole

17   product using stability study, and that's what FDA requires.

18   Q.   But the actual data that's available in a patent trial

19   like this is much more limited than the data that would be

20   available if we had pH and impurity readings from all of the

21   commercial batches; correct?

22   A.   What do you mean all of the commercial batches.

23   Q.   Dr. Park, if we had a thousand commercial batches that

24   Eagle has, is planning to make, we'd have a lot more

25   information about the commercial product and how it works in

Park - cross

1   the real world than we can get from just looking at the

2   handful of batches that have been made to date; correct?

3   A.   Once again, ANDA, all NDA process such that product is

4   represented by the stability study. Nobody measured every

5   single vial of every batch. If you measure every vial of

6   the whole batch, there's nothing to sell. That's not the

7   point of a production FDA. FDA required testing certain

8   number of samples to represent the batch. That's what FDA

9   requires.

10   Q.   And how many batches were tested using a pH of 3.64 at

11   release using the optimized process that Eagle has claimed

12   in this case?

13   A.   Well, I can go back to the table. I cannot recall

14   that, but let's put the table -- I gave you the table

15   before. Right? Let's look at the table and go through it

16   and we can find out.

17   Q.   Okay. Let's do that. Go to the Elmo. All right.

18   Thwarted again. It's not my forte here. I broke the

19   screen?

20   THE COURT: I don't think you broke it, but

21   check it out at the next break. Certainly, everybody is

22   welcome to try out the equipment.

23   BY MR. BLACK:

24   Q.   All right. Let's try again. Okay.

25   THE COURT: I think you may have it fixed.

Park - cross

1   MR. BLACK: Do you have it? All right. Well,

2   riveting cross, I know. Let's go to DTX-993, which is the

3   summary of the data.

4   BY MR. BLACK:

5   Q.   All right. This is a summary of the data that you

6   referred to a moment ago.

7   Do you have it in front of you? Can you read

8   it?

9   A.   Yes.

10   Q.   Okay. Now, I understand it's your position that

11   batches SVA001 through 6 are no longer representative of the

12   commercial product; correct?

13   A.   No. I said no longer represent pH of the commercial

14   product.

15   Q.   No longer represent the pH of the commercial product.

16   All right. So let's take a look at this chart

17   and we'll start with SVA7, and what it shows in the first

18   column, there's an initial pH at release; is that correct?

19   A.   Yes.

20   Q.   And then the second column we have one-month data,

21   then three-month data, et cetera; correct?

22   A.   Yes.

23   Q.   All right. So if we start with SVA7, the initial pH

24   was 3.50; is that correct?

25   A.   Yes.

Park - cross

1   Q.   And if you look at that, you'll see that there are a

2   large number of values which are above 3.50, including 3.54

3   right at the one month date.

4   Do you see that?

5   A.   Yes.   Several numbers, yes.

6   Q.   Okay.   So 3.54, 3.51, 3.51, 3.55, 3.51, 3.51, 3.52,

7   3.51, 3.51 are all values which are above the release value

8   for SVA007.

9   Do you see that?

10   A.   What do you mean above a release value?

11   Q.   The initial value at 3.50 is less than nine values

12   that were recorded during the shelf life of SVA7; is that

13   correct?

14   A.   As I understand release value, 3.4 to 3.6.

15   Q.   No, no.   I'm asking a question.   This is actual data?

16   A.   Right.

17   Q.   You said we have to decide this case based on actual

18   data; right?

19   A.   Absolutely.

20   Q.   And you say this data is representative of the actual

21   commercial product; correct?

22   A.   Yes.

23   Q.   And you asked me to put this table in front of you to

24   help answer the question; right?

25   A.   Yes.

Park - cross

1   Q.   And SVA7 released at 3.50; is that correct?

2   A.   Yes.

3   Q.   And then Eagle and AMRI got nine values that were

4   above 3.50 during the shelf life; right?

5   A.   I would say around 3.50.

6   Q.   Sir, the values recorded in this table, which is

7   evidence that was provided by Eagle, indicates that there

8   were nine values above 3.50 that were recorded in their

9   stability data; is that correct?

10   A.   Above 3.50, yes.

11   Q.   Yes.

12   A.   But, again --

13   Q.   And the highest value -- the highest value above was

14   3.55, which was an increase of .05 over release; is that

15   correct?

16   A.   Right. And you can see at 18 months it goes down to

17   3.46. Below 3.5.

18   Q.   Let's try to do it this way. I will ask the questions

19   and you can answer the questions I've asked and if your

20   counsel wants to follow up with additional information, they

21   have an opportunity to do so. Would that be okay?

22   A.   Yes. Thank you.

23   Q.   Thank you.

24   Now, SVA08 started at a release of 3.52; is that

25   correct?

Park - cross

1   A.   Yes.

2   Q.   And it had release values of 3.53, 3.53, 3.53, 3.53

3   and 3.53, five different release values -- excuse me, five

4   different values during stability that were above the

5   release value; is that correct?

6   A.   You mean compared to 3.52?

7   Q.   Yes.   I'm comparing the release value against the

8   shelf life.

9   A.   Yes.   Compared to 3.52, 3.53 is above, yes.

10 Q.   Right.   That was a difference of .01 maximum; is that

11 correct?

12 A.   Yes.

13 Q.   Okay.   Then SVA9 started at 3.48 and then immediately

14 within a month got a value of 3.52; right?

15 A.   Yes.

16 Q.   And then at three months they got values of 3.52 and

17 3.53; right?

18 A.   Yes.

19 Q.   And then 3.50 and lots of other values, including 3.54

20 at 12 months; is that correct?

21 A.   Yes.

22 Q.   In fact, every single value for SVA9 was above the

23 release value of 3.48; isn't that right?

24 A.   Compared to 3.48, yes.

25 Q.   All right.   And the maximum increase recorded here is

454

Park - cross

1   .06; right? Difference between 3.48 and 3.54?

2   A.   Yes.

3   Q.   Now, SVA11, we have a double asterisk there, because

4   we had six starting values. I'm going to come back to that

5   and address that later.

6   SVA12 and 13, those are recent additions to the

7   case. SVA12 started at 3.48 and immediately jumped up to

8   3.51, 3.51, 3.52; right?

9   A.   I agree.

10 Q.   Thank you.

11 A.   But I don't like the description immediately jumped.

12 Q.   Okay. Release value was 3.48, the recorded release,

13 the recorded value of stability at one month by Eagle and

14 AMRI was 3.51. The recorded value by Eagle and AMRI at

15 three months was 3.51 and the recorded value by Eagle and

16 AMRI at six months was 3.52?

17 A.   Yes.

18 Q.   Agreed?

19 A.   Yes.

20 Q.   Thank you.

21   SVA13 -- oh, I forgot something. The difference

22 between 3.48 and the maximum value, we only have six months

23 of data, is already .04; is that correct?

24 A.   Yes.

25 Q.   All right. And on SVA13, the release value was 3.49

1   and the first recorded value at one month during stability

2   was 3.53; is that correct?

3   A.   Yes.

4   Q.   And then 3.54 and then 3.53; is that correct?

5   A.   Yes.

6   Q.   And the increase from release to the maximum number

7   3.54 is .05; is that correct?

8   A.   Yes.

9   Q.   And so we have a bunch of values based on the

10   so-called optimized batches which show significant drift

11   between the time of release and the stability testing.

12   Agree or disagree?

13   A.   There is a drift, but I would not describe it as a

14   significant drift, because values are all around 3.51, 51,

15   50, 52.

16   Q.   There is a drift, and therefore if Eagle releases a

17   product at the upper end of the -- upper end of the pH range

18   of their approval 3.64, this product will go into the

19   commercial world at a pH above 3.64; is that correct?

20   A.   No, no, no, that's not true. We heard yesterday Dr.

21   Aungst clearly indicate that pH 3.64 will not be released

22   because it doesn't meet the in-process specification. He

23   spent hours to explain that.

24   Q.   Dr. Aungst testified, I believe, that there would be

25   nothing to prevent the release of a batch that met the

Park - cross

1   in-process spec and the release spec; isn't that right?

2   A.   That is not how I understand. Could you explain to

3   me?

4   Q.   Sure.

5   THE COURT: Well, wait. I don't want him to

6   testify and I don't want you to ask him questions.

7   THE WITNESS: No, no. To clarify.

8   THE COURT: I get you, and it's fair to ask for

9   a clarification if you don't understand something. Let's

10   keep it with questions.

11   MR. BLACK: Sure.

12   BY MR. BLACK:

13   Q.   What is your understanding of the value of the

14   in-process specification top end?

15   A.   The top end specification, 3.42 to 3.54.

16   Q.   And therefore the top end would be 3.54; is that

17   correct?

18   A.   Yes.

19   Q.   And the release specification goes up to 3.64; is that

20   correct?

21   A.   Yes.

22   Q.   So a product that meets the in-process specification

23   when it's made of 3.54 and then is released at 3.64 would be

24   permissible under the ANDA; is that correct?

25   A.   That's the point I like to make. Thanks for pointing

Park - cross

1   it out. If 3.54 is met as an in-process specification, I

2   don't see how all of a sudden it jumped to 3.64. All the

3   data you describe here, whether they show .17, I don't see

4   it that way, so my answer is no.

5   Q.   Dr. Park, step by step. We'll get there. Right now I

6   just want to know your understanding that if there is a

7   product which has a value of 3.54 in-process spec and if

8   that product drifts to 3.64 and is released at 3.64, the

9   ANDA permits Eagle to sell that product; is that correct?

10   A.   Well, that I cannot agree with you.

11   Q.   Okay. I'm not asking you whether you think as a

12   matter of science that's going to happen. We'll get there.

13   I'm just asking your understanding of how the specifications

14   work.

15   The way the specifications works is Eagle is

16   allowed to make a product that just meets the in-process

17   spec at 3.54 and they can still sell it and release it at

18   3.64. Right? That's what the FDA will permit them to do.

19   That's the evidence in this case, isn't it?

20   A.   Well, again, I don't know what FDA will do, but if

21   that's the case, yes, but, again I don't see how --

22   Q.   Thank you for your answer. I would appreciate it very

23   much so, very much if you would answer my question yes, no,

24   or if you have a question about my question, feel free to

25   ask for a clarification, but not add extraneous material.

Park - cross

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 1   Your counsel will have an opportunity.

 2             All right.  So we've established two things --

 3   that the FDA would allow the sale of that 3.64 product and

 4   that there's upward drift between release and stability in

 5   the ANDA product, which we will see in commercial batches;

 6   is that correct?

 7   A.    No, I don't think so.  First of all, as I said, I

 8   don't know what FDA will do.  Also, second, I don't see the

 9   .1 upward drift.

10   Q.    All right.  Well, you agree that we've seen upward

11   drift in SVA7 to 13 in the range of .05 to .06.  Those are

12   real world values; right?

13   A.    .06, we were talking about 3.48 to 3.54.  Right?

14   Q.    Yes.

15   A.    Yes.

16   Q.    Okay.

17   A.    .06 went from 3.48, so, again, I don't see how it

18   relates to .1 of which.

19   Q.    Okay.  I'm not sure what that meant, but we can move

20   on to the next point.

21             All right.  I've got another chart here.  Okay.

22   If you will take a look -- if we can pull up DDX-2-39 from

23   Dr. Park's slide, slide 39.

24             Okay.  We've got our marker on release to

25   stability .05 to .06.  Let's talk about increase in pH from
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1   any in-process spec to the release.

2   So in-process and release happen -- the release

3   testing happened very close together in time; is that

4   correct?

5   A.   Yes.   Samples are collected the same place, same time,

6   yes.

7   Q.   Right.   And we have on the chart here, and this comes

8   from DTX-993 and we're using slide DDX-2-39, we have the

9   pre-filtration, post filtration, and then the initial values

10 which, for each of the batches from SVA7 to 13, which you

11 said are representative of the commercial batch; correct?

12 A.   Yes.

13 Q.   Okay.   So if we look at the post filtration column and

14 we look at the initial data for SVA11, we see something

15 interesting that you commented on, which is that between the

16 post filtration value of 3.50 and release, we see pH values

17 that are in a range of one-tenth of a pH unit; is that

18 correct?

19 A.   I'm sorry.   The question was one-tenth of a pH unit?

20 Q.   You testified before that the initial values for SVA11

21 were in a range of one-tenth of a pH unit to the variation;

22 is that correct?

23 A.   One-tenth means .1 variation.

24 Q.   Yes.

25 A.   Yes.

Park - cross

1   Q.   By the way, do you think that variation is caused by

2   the product, by operator error or just random variation in

3   the vial?

4   A.   I think it's accurate. I think it's due to the

5   measurement itself.

6   Q.   Yes. So just to be clear -- I'm sorry. Did I cut you

7   off?

8   A.   Vials.

9   Q.   Oh?

10 A.   Because of the vial pH itself.

11 Q.   Okay. Just to be clear, initial are the release

12 values and post filtration is the process, in-process value;

13 is that correct?

14 A.   Yes, in-process.

15 Q.   All right. All right. So at least between the 3.50

16 and SVA11 in-process and the highest initial values, we see

17 a difference of .06 and .07; is that correct?

18 A.   In a 3.50, 3.56 and 3.57.

19 Q.   Yes?

20 A.   Yes.

21 Q.   And those are possible values that have actually been

22 experienced in the real world by Eagle; is that correct?

23 A.   Yes.

24 Q.   Okay. And then for the next batch, SVA12, we have a

25 3.44 in-process reading and then three other readings that

1   are higher, including a 3.50 reading that shows an increased

2   value of .06; is that correct?

3   A.   Correct.

4   Q.   And then SVA13, we've got 3.49 and then one value

5   that's above at 3.50; is that correct?

6   A.   Correct.

7   Q.   Okay. So it's representative of the commercial

8   batches to expect a difference in-process versus the release

9   reading could be in the order of .07 or .06, because that's

10   the data that we have now; is that correct?

11   A.   Yes.

12   Q.   And, of course, we only have limited data. If we had

13   a hundred different sets of this data, we'd see --

14   undoubtedly, we would see values that are higher than these

15   values?

16   A.   No, I don't think so.

17   Q.   You don't think so. You think if we did this

18   experiment 100 times, experiment where the variation is .1

19   of a pH unit, that you would never see a value higher than

20   3.57 in those 100 experiments?

21   A.   It may be higher than 3.57 or 3.58, but if you

22   increase the number of measurements, so the value will be

23   narrower and narrower close to the real value, which is

24   3.50.

25   MR. BLACK: Your Honor, now would be a good time

Park - cross

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 1    to break so I can fix the Elmo for one thing.

 2                THE COURT:  Oh, okay.  That's a good idea.

 3    Let's do that.

 4                Can you step down for a minute, Dr. Park?

 5                THE WITNESS:  Yes.

 6                THE COURT:  You can head off early.  Because you

 7    started cross-examination, you can only speak with the

 8    lawyers about what is for lunch.  Don't talk about your

 9    testimony.

10                THE WITNESS:  Absolutely.

11                THE COURT:  Okay.  Thank you very much.

12                THE WITNESS:  Thank you.

13                (Witness excused.)

14                THE COURT:  I just want to quickly see the

15    lawyers.  Then we'll break for lunch.

16                How long do you all want?  Is 30 minutes good or

17    do you need more?

18                MR. BLACK:  Half-an-hour would be great.

19                THE COURT:  Are you sure?  Long enough?  That

20    will be enough?

21                MR. BLACK:  I will take more if you give it to

22    me.

23                THE COURT:  I prefer to go 30, but if you want

24    to go --

25                MR. BLACK:  I would like to go a little longer.
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Park - cross

 1   This is obviously important cross.

 2   THE COURT: Okay. So do you want to, like, ten

 3   of?

 4   MR. BLACK: That would be great. Thank you,

 5   Your Honor.

 6   THE COURT: Are you all good with that?

 7   MR. HALES: We're fine with that.

 8   THE COURT: All right. Just a quick point. I

 9   just want to make sure. I see people were fighting over it

10   yesterday. I think you are all on the same page. You all

11   agree initial is the same as release. Fair?

12   MR. BLACK: Yes.

13   THE COURT: And that the post-filtration it

14   sounds like is really the end of the on-process. Right? Do

15   you all agree on that?

16   MR. BLACK: Yes.

17   THE COURT: You don't have to fight over that

18   anymore?

19   MR. BLACK: Yes.

20   THE COURT: You were fighting over it yesterday.

21   MR. BLACK: I didn't think we were fighting over

22   it.

23   THE COURT: I think the testimony will bear it

24   out.

25   MR. HALES: It might be it was the end of the

1   in-process, the start of the release.

2   THE COURT: So then that brings up -- so that's

3   what remains then. I thought there has to be, and I think

4   the last line of questioning showed there's some distinction

5   between in-processing and release because they don't match

6   up there. Right? And so I thought post-filtration would

7   represent the end of the processing for purposes of

8   measuring pHs.

9   MR. BLACK: My understanding is that -- yes.

10   The issue -- I think the confusion is they do an in-process

11   test. At the end of the process, they're going to have to

12   meet 3.54.

13   THE COURT: All right.

14   MR. BLACK: They do a release test, which is

15   based on vials taken not exactly the same time, same day,

16   and then they release the product. And the product -- the

17   release is actually a -- they sign a piece of paper that has

18   a release date on it.

19   THE COURT: Right. And it has to be no more

20   than 3.6 at that point.

21   MR. BLACK: Right.

22   THE COURT: And the in-processing --

23   in-processing, is that the right one?

24   MR. BLACK: In-process.

25   THE COURT: In-process there's really two

Park - cross

1   measurements, but the one that counts is the post

2   filtration? Is that right?

3   MS. WACKER: They all count. There's one that

4   is measured that's still the same. You take out the

5   product. It's in all of the vials and some of the vials are

6   used for the post-filtration test, but it's from the vials.

7   Some of them are used for --

8   THE COURT: But what's represented to the FDA --

9   MR. BLACK: Post filtration.

10   THE COURT: I thought there were times when

11 somebody was just saying the in-processing rate or spec and

12 they don't say whether it's post filtration.

13   MR. BLACK: I think we've mostly been talking

14 about the post filtration except in Dr. Park's testimony

15 when he went into a little more granular level of what they

16 are doing with the tank.

17   And they actually take multiple readings that

18 aren't reported to the FDA while they're fiddling and trying

19 to get the pH right. Then they take a pre-filtration test.

20 They lock it down. Then they filter it to get out any

21 microbes.

22   They do a post-filtration test before they fill.

23 They put that value, that has to go to the forms, that goes

24 to the FDA. Then they take vials that are filled and do a

25 release test.

1   THE COURT: I think everybody agrees --

2   MS. WACKER: That was not accurate.

3   Post-filtration is taken from vials. I think you misspoke.

4   Right.

5   THE COURT: But maybe I'm just misremembering

6   things, which happens a lot. Is there ever a time where

7   somebody said to the FDA, here's the in-processing pH spec?

8   MS. WACKER: Yes. It is part of the proposed

9   batch records.

10   THE COURT: And when they do that, are they

11   reporting the post-filtration spec? What are they reporting

12   at that point?

13   MS. WACKER: All of it, the pH adjustment.

14   THE COURT: That sounds like three numbers as

15   opposed to one number.

16   MS. WACKER: They report all of the different --

17   THE COURT: So they never just report an

18   in-processing pH level. You're saying they always report

19   the three components -- I'm sorry, three separate readings.

20   What are you telling me? Get some clarity.

21   MS. WACKER: I just want to make sure we're on

22   the same page. The proposed commercial batch record is

23   something that went into the FDA that said here are the

24   specifications we're using for each of those steps. Does

25   that make sense? But for the factors that are going out,

Park - cross

 1   like if we were proving going out in the future, I don't

 2   believe that those in-process, like the adjustment, all of

 3   that would be reported to the FDA.

 4   THE COURT: I got that from the video testimony.

 5   MS. WACKER: Yes.

 6   THE COURT: I got what would ultimately. I'm

 7   talking about though what's being reported now and what is

 8   being represented will be met.

 9   MS. WACKER: What is being represented will be

10   met because what's in that proposed commercial batch record

11   that has an adjustment pH, stabilization pH, in-process

12   of --

13   THE COURT: It has both and they separate them

14   out.

15   MS. WACKER: Correct.

16   THE COURT: They don't conflate --

17   pre-filtration, post-filtration.

18   MS. WACKER: Correct.

19   THE COURT: All right. But we can at the very

20   least equate initial with release. Nobody is going to

21   dispute that.

22   MS. WACKER: Yes.

23   THE COURT: All right. Good. We'll come back

24   at 12:50. Thank you.

25   (Luncheon recess taken.)

Park - cross

1   - - -

2   (Afternoon session, 12:56 p.m.

3   THE COURT: All right. Please be seated.

4   Just because of scheduling, I'm five minutes

5   late. I have a call with a Third Circuit committee at

6   8:00 o'clock tomorrow morning. I will not be able to break

7   it off if it doesn't end at 8:30. It hopefully will. If

8   you all could be ready to go at 8:30. Thank you.

9   Ready, Mr. Black?

10   MR. BLACK: Okay. Thank you, Your Honor. We

11   got the Elmo working.

12   THE COURT: Oh, good.

13   MR. BLACK: So I've been warned by my team not

14   to use a red Sharpie on the Elmo like I did in Federal Court

15   in Texas and I almost ended up in jail. I will be more

16   careful here now.

17   BY MR. BLACK:

18   Q.   And I have this slide here now which is what we would

19   have done had the Elmo been working, which summarizes your

20   testimony from before about batches SVA7 through 13.

21   What the slide shows, I've highlighted in green

22   the values for stability, which were above the release

23   values. I've circled in each case the highest value for

24   instability and then I put on the right-hand side the

25   difference between the initial and stability values at the

Park - cross

1   highest number on the right-hand column. Does that look

2   accurate to you?

3   A.   I think so.

4   Q.   Thank you. Okay.

5   So you had a slide with a ruler in it and we've

6   made up a similar slide.

7   All right. Now, just before the break, Judge

8   Connolly asked a couple of questions to clarify what is

9   in-process release and the different numbers that have been

10   discussed because the process of making the product is a

11   little complicated and there are a lot of places where pH

12   readings are made. And I just want you to clarify that the

13   in-process specification, the final in-process specification

14   number is taken at post-filtration; correct?

15   A.   Correct.

16   Q.   And in the process optimization confirmation batches,

17   and this is your slide 30, the specification that they used

18   was 3.42 to 3.50; correct?

19   A.   Correct. 50.

20   Q.   50 for the process optimization batches. The top end

21   number is 3.50; correct?

22   A.   3.50?

23   Q.   Yes. Process optimization.

24   A.   I'm sorry, yes. I was looking -- yes. 3.50, yes.

25   Q.   And those are the batches regarding which we were

1   using to calculate the data; correct? Let me rephrase.

2   A.   I'm sorry.

3   Q.   Some of the data that you've been showing the Court

4   comes from process optimization and confirmation batches; is

5   that correct?

6   A.   Yes.

7   Q.   And when those batches were made, the in-process

8   specification that was used was 3.42 to 3.50?

9   A.   Yes.

10   Q.   On the right we have yellow. This is your slide, the

11   intended commercial production batches. And there, the

12   specification has been broadened slightly to be 3.42 to

13   3.54; is that correct?

14   A.   Yes.

15   Q.   And that's because they want a little bit more leeway

16   when they make a whole bunch of commercial batches to make

17   sure that if something goes wrong, they've got a little bit

18   of extra room on the pH; is that correct?

19   A.   I don't know what their thought was. The fact that

20   3.54 is way less than 3.64.

21   Q.   Okay.

22   A.   And as Eagle's documents show, their goal was to meet

23   the pH target around 3.50. So this is well within the --

24   Q.   That may have been their goal at one point, but I

25   think we can agree that the actual commercial batches, 3.54

1   is the number that they are telling the FDA they want

2   approval for; right?

3   A.   Yes.

4   Q.   Okay. And they are also still telling the FDA they

5   want approval for release of 3.64; is that correct?

6   A.   I'm not sure what approval you're looking at.

7   Q.   Have you ever seen Eagle propose a release number that

8   was less than 3.6 rounded, i.e., 3.64?

9   A.   Eagle's release specification is 3.4 to 3.6, so 3.6

10   may include 3.64, but, again, going back to Dr. Aungst --

11   Q.   Thank you. Excuse me, sir. I really hate to cut you

12   off. It's very rude, but I would appreciate it if you would

13   answer the question that I asked. The release specification

14   in the current ANDA that the Court has to evaluate is 3.6

15   rounded, i.e., 3.64; is that correct?

16   A.   3.64, yes.

17   Q.   So Eagle is asking the FDA to approve a product that

18   when they are making it in the vats and when they pull the

19   vial out to do the in-process spec can be as high as 3.54,

20   but by the time they release, it can be as high as 3.64; is

21   that correct?

22   A.   I think so.

23   Q.   Right. Now, Eagle had the option, right, of saying to

24   the FDA, you know, we don't need all of that extra room and

25   changing their release spec to the 3.54; right?

Park - cross

1   A.   I don't know whether they had an option or not.

2   Q.   But if they did that, we'd have another case here;

3   right? Because there would be a very significant difference

4   between 3.54 and the infringing range; correct?

5   A.   Well, I don't know -- frankly, I don't know what you

6   are talking about. But 3.54 is well within the

7   specification, so I don't know what is the issue here.

8   Q.   And if they reduced the pH to 3.54 release, they

9   dramatically reduce the chance that any batch would ever

10   reach 3.65; is that correct?

11   A.   Again, I don't know whether it's reduce the chance or

12   not. Specification right now is well within the spec, so I

13   don't know what your concern is.

14   Q.   Isn't Eagle taking a bit of a gamble here by asking

15   the FDA for permission to release products that could be as

16   high as 3.64 when the patents at issue in this case, which

17   they've known about for three years, have a pH of 3.7 in the

18   range?

19   A.   Again, I don't know whether Eagle is taking a gamble

20   or not. Clearly, 3.64 is a range, but not 3.7.

21   Q.   Okay. Thank you.

22   All right. So let's talk about the commercial

23   batches. And I've got a ruler here a little bit like the

24   one that you put up before. We've got three items on this,

25   on this chart.

Park - cross

1   First we've got the in-process spec. Now, for

2   the commercial batch, so the top end in-process spec is

3   3.54; is that correct?

4   A.   Yes.

5   Q.   All right. I will color that in. Now, we've seen the

6   data just before lunch from SVA11 that showed that the Eagle

7   product can go from the in-process spec to a release spec

8   and we saw an actual batch with a different, an increase of

9   .07 in those values; is that correct?

10   A.   Can you remind me again exactly what you're referring

11   to?

12   Q.   Sure. The SVA11 data. All right. The SVA11 data

13   showed that the -- we don't have the -- sorry. We need to

14   get the -- SVA11 had a pH of 3.50 at the in-process spec and

15   then it had six different readings at release, the highest

16   of which was 3.57.

17   Do you recall that?

18   A.   Yes.

19   Q.   Okay. Thank you.

20   All right. So if we go from in-process with the

21   data from that batch up seven tenths, 3.54 plus .07 is 3.61;

22   is that correct?

23   A.   If you add --

24   Q.   Is that correct?

25   A.   Yes. I'm going to answer. If you added to 3.54,

Park - cross

1   0.07, yes.

2   Q.   And we also saw upward drift during the shelf life on

3   the order of .05 and .06 in multiple batches of the

4   optimized product; is that correct?

5   A.   Yes.   Around 3.50.

6   Q.   Yes.   No, that's not my question.   My question was

7   here we showed it from release through product life.   We saw

8   increases of .05, .04, .04, .06, .04, .05 in the data that

9   you say is representative of the batch between release and

10   shelf life; correct?

11   A.   Yes.

12   Q.   So if we were to add to the 3.61, .05 or .06, we'd be

13   in the infringing range, wouldn't we?

14   A.   The highest --

15   Q.   Yes or no, sir?   Yes or no, sir?   Would that value be

16   within the infringing range?

17   A.   The value of the infringing range --

18   Q.   Thank you.

19   A.   -- but your calculation is wrong.

20   Q.   Eagle is maintaining the right to sell a product that

21   releases while in commercial manufacture at a pH of 3.64; is

22   that correct?

23   A.   Again, I) don't know what -- what right they have.

24   Q.   Okay.   Let's talk a little bit about the refrigerated

25   data and, again, the question of optimization.   This is your

Park - cross

1   slide 19, a little blurry, but for my purposes, it won't

2   matter that much. And this shows, I believe you said, the

3   pH behavior of the registration and characterization batches

4   at the top; is that correct?

5   A.   Yes.

6   Q.   And the pH behavior of the optimization and PPQ

7   batches at the bottom; is that correct?

8   A.   Yes.

9   Q.   And you kind of crunched the scale a little bit, so

10   it's hard to see, you know, exactly what's going on here,

11   but you testified that this is -- these pH profiles are

12   different, these are different behavior; is that correct?

13   A.   Yes, I said that.

14   Q.   And so you have two batches with the identical

15   component made by the same people at the same plant under

16   the same ANDA and you have very different pH profiles, don't

17   you?

18   A.   That's not true.

19   Q.   Well, are the pH profiles different?

20   A.   Usually not changing in manufacturing process.

21   Q.   Okay. Go ahead. So you have two different pH

22   profiles that have the same formulation, the same

23   manufacturer, a different manufacturing process; right?

24   A.   Correct.

25   Q.   A little bit like giving the ingredients to a cook and

Park - cross

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 1    seeing what you get.  You might give the same ingredients to

 2    me and my wife, but the omelet would come out a lot

 3    differently.  Fair analogy?

 4    A.    I don't understand your point.

 5    Q.    Okay.  I will move on.  The point is that the pH

 6    properties of the formulation, an identical formulation can

 7    be very different based on the characteristics of the

 8    manufacturing process; correct?

 9    A.    Again, as I explained, stirring is much longer for

10    optimization process compared to registration batches.  So

11    longer stirring make mixing more homogeneous.  That's why

12    Eagle has such a narrow pH reading.

13    Q.    Right.  But all I'm saying is the manufacturing

14    process in your view has significantly contributed to

15    changing the pH profile of the Eagle product; correct?

16    A.    Yes.

17    Q.    Okay.  And have you examined the manufacturing process

18    for Vasostrict?

19    A.    Which Vasostrict?

20    Q.    Either one?

21    A.    You mean API?

22    Q.    No.  You just testified that the manufacturing process

23    can make a big difference in the pH profile of identical

24    products by the same manufacturer in the same plant and I'm

25    just wondering if you have looked at Par's manufacturing
```

Park - cross

1   process to compare it to the manufacturing process used by

2   Eagle, because I didn't see any of that in your report.

3   A.   I'm so sorry. I don't understand your question.

4   Q.   Have you reviewed Par's manufacturing process? I

5   didn't see anything in your report about it. I didn't hear

6   any testimony about it.

7   A.   No, no. I explained that during my direct, I went

8   through the process for the ANDA.

9   Q.   Have you made a detailed analysis and provided a

10   report on Par's manufacturing process --

11   A.   Oh, Par's?

12   Q.   Par's, yes.

13   A.   I'm sorry. No. Par. No, I don't.

14   Q.   So therefore since the manufacturing process can

15   affect the pH profile, even by the same manufacturer, i.e.,

16   Eagle, it follows that the manufacturing process of Par

17   could affect the pH profile of Par's product; is that

18   correct?

19   A.   If they change, yes, it could.

20   Q.   And therefore it would be wrong to say that the

21   products are identical simply because they're generic

22   because the pH profile, which is what is important to this

23   case, is dependent on the manufacturing process, not just

24   the ingredient in the product; is that right?

25   A.   I'm not sure what you are comparing, but generic and

Park - cross

1   RLD compare the active ingredient, excipient and others and

2   whether it's safe or not based on ingredients and

3   excipients. So other than that, I don't know what you are

4   talking about.

5   Q.   The FDA doesn't go through and compare the

6   manufacturing processes of Eagle and Par. In fact, those

7   are closely held secrets; is that correct?

8   A.   That I don't know.

9   Q.   Okay. There are other differences between original

10   Vasostrict and the Eagle product, including the impurity

11   profile; correct?

12   A.   Impurity profile depends on the API.

13   Q.   Right?

14   A.   So API -- unless getting the API from the same source,

15   impurity profile may be different.

16   Q.   And you're aware that the source for Eagle's API is

17   different from the source for Par's API?

18   A.   I don't know, but maybe.

19   Q.   And if they were different, then you would see

20   different impurities in the formulation and different

21   amounts of impurities; right?

22   A.   Right.

23   Q.   And the FDA goes through and they decide whether or

24   not the differences are relevant to safety and

25   effectiveness; is that correct?

Park - cross

 1   A.   Again, what FDA does, I don't know.

 2   Q.   Okay. Are you aware that Eagle is sending data to the

 3   FDA relating to impurities and other matters relating to

 4   original Vasostrict?

 5   A.   That I don't know. I don't remember.

 6   Q.   I'd like you to take a look at one of the documents

 7   that's in your binder, DTX-133. I'm not going to switch

 8   because I don't want to lose my Elmo.

 9   A.   DX-133?

10   Q.   Yes.

11   A.   Yes.

12   Q.   And this is a -- this is a compilation of

13   communications between Eagle and the FDA and consistent with

14   the Court's instructions, we are not going to try to admit

15   the entire document, but there are two pieces of it I would

16   like to refer you to.

17   A.   Yes.

18   Q.   So if you take a look at page 36, this is an e-mail or

19   letter, it's not clear, from Adrian Hefner, Chief Medical

20   Officer at Eagle, to Charmaine Lintildus, Regulatory

21   Business Process Manager at FDA.

22   Do you see that?

23   A.   Yes.

24   THE COURT: I'm sorry. I'm lost. What page is

25   it?

1   MR. BLACK: Oh, it's DTX-133.0036.

2   THE COURT: Okay. Thank you.

3   MR. BLACK: I will put it up on the Elmo.

4   BY MR. BLACK:

5   Q.   And if you look to the fifth paragraph, it says, Eagle

6   would like to know if it is acceptable to the FDA to perform

7   the comparative analysis of the generic product versus the

8   current product RLD in the market which differs slightly in

9   formulation provided in the table below and in the table,

10   the image of which was cut off here, your exhibit.

11   Do you see that?

12   A.   Yes.

13   Q.   That was a request by Eagle to perform their testing

14   for FDA approval against the reformulated Vasostrict because

15   they didn't have original Vasostrict vials to work with

16   anymore; is that correct?

17   A.   That I don't know.

18   Q.   Okay. And then if you go back two pages to page 34,

19   DTX-133-0034, we have the FDA's response at the bottom of

20   the page in the block quote, and it says, "It is recommended

21   that you conduct the comparative studies requested in the

22   CRL Section B, questions 1, 2 and 3, using samples of both

23   presenting of the current RLD formulation, i.e., both the

24   one milliliter single dose and ten-milliliter multiple dose

25   presentation."

1   And this letter is dated September 26, 2018. So

2   the current RLD would be reformulated Vasostrict; is that

3   correct?

4   A.   What is the current -- current RLD formulation, both

5   ml and ten ml presentation.

6   Q.   The current RLD as of the date of this communication,

7   September 26, 2018, was reformulated Vasostrict; is that

8   correct?

9   A.   Yes. As I read again, it is recommended that you

10   conduct a comparative study because original Vasostrict

11   was not available anymore, so it used a current Vasostrict.

12   Q.   Yes.

13   A.   Yes, that's what it says.

14   Q.   And you have not seen any evidence that Eagle refused

15   to cooperate with the FDA and do the testing based on the

16   current RLD, reformulated Vasostrict?

17   A.   I have no information, but I guess not.

18   Q.   Okay. Let's talk about your validity opinion.

19   You agree, do you not, that the person of

20   ordinary skill is someone who has some formulation

21   background in peptides; is that correct?

22   A.   Yes.

23   Q.   So let's imagine such a person sitting in their office

24   in the bowels of a pharmaceutical company and gets a phone

25   call from the bosses upstairs and the researcher is told,

Park - cross

1   we're going to try to make a version of Vasopressin product.

2   Can you get to work gathering some information? Imagine

3   this person is a POSA. Okay?

4   A.   Yes.

5   Q.   The first place the POSA would probably look, one of

6   the first places, would be the USP to see what the basic

7   information is available about the drug; is that right?

8   A.   Before that, a POSA would look into RLD if they want

9   to make a copy.

10   Q.   I was thinking that would be second, but first.

11   Sounds good. First you start with the RLD and what's

12   available is the label; is that correct?

13   A.   Yes.

14   Q.   On the priority date, that label would have said in

15   the label for original Vasostrict, it would have said pH 3.4

16   to 3.6; is that correct?

17   A.   Label, yes.

18   Q.   Yes. And the USP monograph would have said 2.5 to

19   4.5; right?

20   A.   Yes.

21   Q.   And the researcher probably would have looked further

22   to see what other information the FDA had published on the

23   drug; right?

24   A.   Yes, I would.

25   Q.   And they would have looked for the biopharmaceutics

1   review and chemistry review which said, make the product at

2   3.4 to 3.6, because if you go outside that range, you're

3   going to have poor stability; right?

4   A.   They would, but again as we discussed, it doesn't

5   really mean that much without data.

6   Q.   That is all that the POSA would have. Right? The

7   POSA wouldn't have the underlying data, but they would have

8   the FDA's conclusion about the data. Is that fair?

9   A.   That's not the only data. We know looking at the

10   patent, other product, they all show the pH values around

11   3.7 and 3.8, so that's not the only data they see.

12   Q.   Your reaction was the POSA would first go to the

13   approved FDA product. Do you really think that the first

14   thing a POSA would look at would be a Lithuanian patent for

15   Vasopressin derived from the pituitary gland of pigs?

16   A.   I didn't say first. It is part of the nature of the

17   search. It's all about the literature search, prior art

18   search in this case.

19   Q.   Right. And the literature search would show a 2.5 to

20   4.5 range and various values within that range you would

21   find Bi and Singh that talks about 3.4, 3.5 and other

22   references; correct?

23   A.   Yes.

24   Q.   Now, you provided some testimony and we had some back

25   and forth with the lawyers about the products that were on

1   the market at the time and the only Vasopressin product on

2   the market on the priority date would have been reformulated

3   Vasostrict; right?

4   A.   I'm sorry. Product on the market?

5   Q.   Yes. The priority date here is February of 2017; is

6   that correct?

7   A.   Yes.

8   Q.   And you have to evaluate a POSA's knowledge and

9   inclination as of February 2017 in doing your obviousness

10   analysis; is that correct?

11   A.   Correct.

12   Q.   And at that point, the only vials that someone would

13   have been able to get of Vasopressin product would have been

14   the reformulated Vasostrict; is that correct?

15   A.   That I don't know.

16   Q.   Okay. Certainly, the vials that were manufactured in

17   2015 that you mentioned before, original Vasostrict, they

18   would have been unavailable by then; is that correct?

19   A.   That I don't know.

20   Q.   Okay. If a POSA did manage to get ahold of some

21   original Vasostrict and test it, you would have to, if you

22   are going to consider that in your analysis, it would be

23   fair to consider all of the vials that were manufactured,

24   the hundreds of thousands of vials, not just the single

25   point value that you hand picked for your obviousness

1   analysis. Is that fair?

2   A.   No, I don't think so. No.

3   Q.   You think it's fair for you to pick one, one record

4   from an internal document at Par that a POSA would have had

5   and include that in your obviousness analysis?

6   A.   If I have a problem, so I need a Vasopressin product,

7   I will take the one approved by FDA. One vial representing

8   the whole batch. So that particular batch is a

9   representation, a representation of the batch that pH was

10   3.7.

11   Q.   But if you went to the market and picked one vial to

12   test, you would have no basis to assert that that vial, that

13   specific vial that a POSA would test would have been outside

14   the label claim of 3.4 to 3.6, do you?

15   A.   But that's what happened, so it would happen.

16   Q.   You are misunderstanding my question. There are

17   millions of vials of Vasopressin sold; is that correct?

18   A.   I don't know how many of them.

19   Q.   You put the sales records into the record, hundreds

20   of thousands or millions of vials are sold; is that correct?

21   A.   Okay. A hundred-thousand I understand, but I don't

22   know millions.

23   Q.   Okay. Hundreds of thousands of vials are sold. Are

24   you assuming that the POSA would know the pH of all of

25   those hundreds of thousands of vials or only the 3.7 test

Park - cross

1   result of the product that you saw in that one document from

2   Par?

3   A.   Of course, I wouldn't know because they did not test

4   the whole thousands of bottles, but one vial, 3.7.

5   Q.   I'm asking for your obviousness analysis, are you

6   assuming that that POSA is starting with the knowledge of

7   that vial of 3.7 or they are starting with the knowledge of

8   all of the vials of Vasopressin, the hundreds of thousands

9   that were sold and all of their pH values?

10   A.   Again, we wouldn't know all the vials or not because

11   nobody tested, but one vial tested was 3.7.

12   Q.   But for the obviousness analysis, the POSA wouldn't

13   know whether -- POSA wouldn't have that information, would

14   they, if it came from an internal Par document?

15   A.   No.   Again, the POSA could measure that particular

16   vial.

17   Q.   By the way, that 3.7 value was taken nine months

18   before the product was sold; correct?

19   A.   I look at the record.   Maybe, yes.

20   Q.   Not maybe yes.   The answer is yes, isn't it?   Do you

21   know that for a fact?

22   A.   Again, I don't recall the exact number, but that may

23   be the case.

24   Q.   And that could have been a value of 3.65 rounded; is

25   that right?   Single vial?

Park - cross

1   A.   That I don't know whether the value was rounded or

2   not.

3   Q.   That value came from a much longer document that had

4   15 or so batches in it; correct?

5   A.   I don't recall how many vials.

6   Q.   Not the vials. There was a batch that you relied

7   on --

8   A.   Yes.

9   Q.   -- and there were about 15 batches that were in the

10   same document that all had pH values listed.

11   Do you remember that?

12   A.   I'm sorry. I don't remember exactly which document

13   you're talking about.

14   Q.   Okay. Do you agree with the statement that Dr. Chyall

15   made in his report in his deposition that Bi and Singh

16   determine the stability of Vasopressin solutions under

17   various pH environments and found favorable stability at a

18   pH of around 3.5? Do you agree?

19   A.   I'm sorry. Could you show the document or can I go to

20   the --

21   Q.   It's a quick -- we can do it if you need to, but I'm

22   just asking whether you agree with the statement. I'm just

23   telling you to be fair, it came from Dr. Chyall's report.

24   Bi and Singh determined the stability of Vasopressin

25   solution under various pH environments and found favorable

Park - cross

1   stability at a pH of around 3.5.

2   Do you agree with that?

3   A.   That's his statement.

4   Q.   I'm saying do you agree with it as someone that

5   reviewed that reference?

6   A.   I don't have a particular reason not to agree, but the

7   vasopressin is stable. Again, without the data, I cannot

8   say. Stable for what?

9   Q.   Do you agree with his statement that pH for

10   Vasopressin formulations had already been optimized at the

11   priority date?

12   A.   No, I don't know what optimization he's talking about.

13   Q.   He testified that -- I'm going to ask you whether you

14   agree with this. In your opinion, the pH of Vasopressin

15   formulations had already been optimized as of the priority

16   date of the patents-in-suit; correct? His answer was, at

17   least by that time, yes.

18   Do you agree with that or disagree?

19   A.   No, I don't agree.

20   Q.   Okay.

21   MR. BLACK: Pass the witness.

22   THE COURT: All right. Thank you. Any

23   redirect?

24   MS. WACKER: No. I just have to move exhibits.

25   THE COURT: Okay. Go ahead. See what Mr. Black

1   says.

2   MS. WACKER: I have a really long list. We also

3   were going to admit all of the citations on that summary

4   document as we discussed at the pretrial conference.

5   I was wondering if maybe it makes sense to

6   confer with Mr. Black during the next break and we could

7   give a written list up. That might be easier than reading

8   100 numbers. I don't think it's a hundred, but --

9   THE COURT: Sounds like a good idea.

10   MR. BLACK: I concur. I have a couple that I

11   want to move in, including my horrible handwriting on this,

12   which he did verify was accurate during his examination, and

13   part of the FDA correspondence, because I know you don't

14   want everything.

15   THE COURT: On that, again, I'm struggling. I

16   told you, and I really appreciate the input of you all,

17   especially that have practiced in Texas and other places.

18   Part of me is like let it in, but then what do

19   we do about when it gets to the Federal Circuit and somebody

20   decides to highlight, oh, we're making a big argument that I

21   never even heard of. And it does happen. I am not saying

22   you all would do it.

23   MR. BLACK: I'm not sure -- I don't understand

24   how it would be proper for them to consider an argument that

25   hadn't been made below about a critical document. If they

1   do, if that is happening in cases, I have not seen it. I'm

2   sure it has happened, but I don't see there's any way to

3   really stop it.

4   THE COURT: Well, I mean, I had a 101 case where

5   a new appellate lawyer, you know, sounded like from a

6   different universe.

7   MR. BLACK: Yes.

8   THE COURT: And the person who argued it in

9   front of me said -- and I'm just going by what my colleagues

10   say, and I have to rely on what my colleagues say. Judge

11   Robinson was the first to institute the rule, but everybody

12   else has followed.

13   But maybe I will just let it go. I mean, there

14   is something to be said for having the entire document

15   admitted. Right?

16   MR. BLACK: Yes.

17   THE COURT: It's in context if a question

18   arises.

19   MR. BLACK: Why don't we do this. We'll work on

20   this outside of the courtroom, but we'll give you a list.

21   If there are issues where either party thinks it's likely to

22   be overbroad to have a big document in, we can talk about

23   it. If there's an issue, we can show Your Honor.

24   THE COURT: Okay. That sounds great. All

25   right. And you're excused. Thank you very much.

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 1                    (Witness excused.)

 2                    THE COURT:  Is Dr. Park going to be asked to

 3    come back?

 4                    MS. WACKER:  He is not.

 5                    THE COURT:  Okay.

 6                    MS. WACKER:  So this concludes our evidence on

 7    noninfringement, so I renew my Rule 52 motion.

 8                    THE COURT:  I will reserve judgment on that.

 9    And then what's next?

10                    MS. WACKER:  We have Dr. Carmen Cross testifying

11    next.

12                    THE COURT:  All right.

13                    MR. KWON:  Your Honor, my name is Sam Kwon

14    and I am counsel for Eagle.  I will be cross-examining

15    Dr. Cross.

16                    THE COURT:  All right.  Thank you.

17                    Do you all want to move whatever books?

18    Somebody probably wants to clear them off.

19                     ...CARMEN CROSS, having been duly

20    sworn/affirmed as a witness, was examined and testified as

21    follows...

22                    THE WITNESS:  Good afternoon.

23                    THE COURT:  All right.  Mr. Kwon?

24                    MR. KWON:  Thank you, Your Honor.

25                         DIRECT EXAMINATION
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Cross - direct

1   BY MR. KWON:

2   Q.   Good afternoon, Dr. Cross.

3   A.   Good afternoon.

4   Q.   Could you please introduce yourself to the Court.

5   A.   My name is Carmen Anthony Cross. I'm a medical doctor

6   with 42 years of experience in the specialty of emergency

7   medicine and trauma critical care.

8   Q.   Dr. Cross, what will you be testifying about today?

9   A.   Are we using slides?

10 Q.   Oh, yes, we are. Let's move to slide 2. Dr. Cross,

11 what will you be testifying about today?

12 A.   I will be testifying about the clinical and historical

13 use of Vasopressin in clinical medicine as well as my review

14 of the patents-in-suit and other clinically pertinent

15 information I was given.

16 Q.   Let's turn to slide 3. Can you please provide an

17 overview of your educational background?

18 A.   Certainly. I received my bachelor's degree in biology

19 from Syracuse University in 1975 and then went on to New

20 York Medical College, where I obtained my doctor of medicine

21 degree.

22   I left in '79 to attend Brown University

23 Affiliated Hospital for the study of internal medicine and

24 critical care, and then left in 1982 to pursue board

25 certification in emergency medicine.

1   Q.   Slide 4, please.   Can you please provide an overview

2   of your educational background?

3   A.   Certainly.   After I left post-graduate training, I

4   started working at an affiliated Albany Medical Center

5   called Columbia Medical Hospital, and there for most of my

6   tenure I served as the chairman of the department of trauma

7   and emergency services as well as a practicing clinical and

8   emergency medical physician.

9   I left in 2000 and started working for the

10   Mohawk Valley Hospital System at St. Elizabeth's Medical and

11   Trauma Center, and I work there to the present day.   There

12   I'm a senior attending in emergency in trauma medicine as

13   well as having other administrative functions.

14   Q.   Dr. Cross, do you use Vasopressin in your course of

15   work?

16   A.   Yes, I do.

17   Q.   How long have you used it for?

18   A.   I've used it for all of the 42 years I've been

19   practicing medicine.

20   Q.   What do you use Vasopressin for?

21   A.   Vasopressin has been used for a number of indications,

22   but mostly as an agent that can increase blood pressure in

23   people who are hypotensive and therefore in shock.

24   MR. KWON: Your Honor, at this time defendants

25   proffer Dr. Cross as an expert clinician, including in the

Cross - direct

1   specialties of emergency medicine and critical care.

2   MR. RHOAD: No objection, Your Honor.

3   THE COURT: All right. Thank you.

4   MR. KWON: Now we're on slide 5.

5   BY MR. KWON:

6   Q.   Doctor, here you have excerpts from DTX-178, DTX-246,

7   DTX-249 and DTX-36. What are these documents?

8   A.   These documents are product labels for Vasopressin.

9   You can see on the left-hand side of the screen, there are

10   three product labels of unapproved generic versions of the

11   drug and on the right, Par's original Vasostrict product

12   label.

13   Q.   Now, which of these products were available for use

14   during your career?

15   A.   All of them.

16   Q.   Do you recall using any of these products

17   specifically?

18   A.   Yes. All of them.

19   Q.   And what were these products used for?

20   A.   Well, since the reference drug in these products was

21   Vasopressin, these drugs were used as a method of increasing

22   blood pressure in shock states as well as other indications.

23   Q.   Now, at the present time, of the four products on the

24   screen, which product is available?

25   A.   The present time, original Vasostrict.

1   Q.   Do you mean original Vasostrict or reformulated

2   Vasostrict?

3   A.   Well, the reformulated Vasostrict.

4   Q.   Now, has the manner in which Vasopressin is used since

5   Par introduced Vasostrict to the market changed during your

6   practice?

7   A.   Not at all.

8   Q.   Now, I want you to take a look at Pitressin, which is

9   on the center of the left side of the slide and original

10   Vasostrict, which is on the right. How are these products

11   relate?

12   A.   When Par submitted its NDA, it expressed a desire to

13   manufacture the generic Pitressin of JHP, which is the one

14   you see in the middle on the left. After it received its

15   NDA, it then marketed the original Vasostrict as an FDA

16   approved drug.

17   Q.   Okay. Let's look at slide 6. Let's now look at Par's

18   submission to the FDA on Pitressin.

19   Here we have excerpts from pages 9 and 30 of

20   DTX-25. What is this document?

21   A.   This is the pre-NDA submission letter authored by

22   Par's predecessor, JHP, that was filed to the FDA in 2011,

23   expressing their desire to manufacture Pitressin.

24   Q.   And what did Par tell to the FDA about when Pitressin

25   became available?

Cross - direct

1   A.   They expressed what clinicians had long known, that

2   this was a 100-year-old drug that had been very well

3   established in the medical profession.

4   Q.   And what did Par tell the FDA about what Pitressin had

5   been used for?

6   A.   They had noted that it had several indications, but

7   most importantly, it's used as a vasodilatory shock pressure

8   agent. In other words, in vasodilatory shock, it can raise

9   blood pressure.

10   Q.   What did Par tell the FDA about the safety and

11   efficacy of Pitressin?

12   A.   They told them that it was a safe and very well

13   accepted medication.

14   Q.   Now, are Par's representations that we just talked

15   about to the FDA regarding use of Vasopressin consistent

16   with how you have used Vasopressin in your practice?

17   A.   Certainly.

18   Q.   Now, following this pre-NDA submission, did Par submit

19   an NDA on Vasopressin?

20   A.   They did.

21   Q.   Let's turn to slide 7. Doctor, here you have an

22   excerpt from page 8 of DTX-42. What is this document?

23   A.   This refers to a clinical reference from Par's NDA for

24   Pitressin.

25   Q.   And has Par performed any clinical trials to support

Cross - direct

1   its NDA?

2   A.   No, not at all.

3   Q.   And what sort of evidence did Par rely on instead?

4   A.   They based all of their evidence solely on

5   pre-existing literature or what you people call prior art.

6   Q.   Let's now talk about the literature Par relied on to

7   support its NDA.   Let's look at slide 8.

8   Now, this slide shows excerpts from page 9 and

9   page ten of DTX-42.   What literature was in the clinical

10   part of Par's NDA based on?

11   A.   Par cited a number of literature references, and

12   particularly you could see on the screen a number of major

13   investigators, and all of these investigators described the

14   dosing that was effective for various states of shock,

15   particularly post cardiotomy shock and septic shock.

16   Q.   Now, during your 40-year practice, were you familiar

17   with any of these references in your course of work?

18   A.   Practically all of them.

19   Q.   And were clinicians like yourself relying on these

20   references regarding use of Vasopressin?

21   A.   Certainly.

22   Q.   Let's now look at the approved product label for

23   original Vasostrict, slide 9.

24   Here we have excerpts from page four of DTX-132.

25   What is this document?

Cross - direct

1   A.   This is the original Vasostrict approved label.

2   Q.   And what was the indication that was approved for

3   original Vasostrict?

4   A.   The original Vasostrict was indicated as a method of

5   increasing blood pressure in patients with distributive or

6   vasodilatory shock, specifically referring here to

7   post-cardiotomy shock and septic shock. They also gave very

8   specific dosage ranges that were drawn directly from

9   pre-existing literature.

10 Q.   And what are those dosages?

11 A.   Post cardiotomy shock, it was recommended and still is

12 recommended to start with a dose of 00.3 units per minute up

13 to a high of 0.1 unit per minute, and for septic shock, a

14 start dose of 0.01 unit per minute to a high of 0.07 units

15 per minute, and all of these would be given by continuous IV

16 infusion.

17 Q.   Now, is a manner in which original Vasostrict is used,

18 including the dosage and indication, different from the

19 unapproved Vasopressin product we just talked about earlier?

20 A.   Not at all.

21 Q.   Okay. Let's take a look at the '209 patent. We're on

22 slide 10 now. What priority date did you apply in forming

23 your opinion?

24 A.   February 7th of 2017.

25 Q.   And what aspects of the '209 patent did you consider

Cross - direct

1   in connection with your opinion?

2   A.   Only the clinical elements of the patents.

3   Q.   And to be clear for the record, what do you mean by

4   the clinical element?

5   A.   The clinical elements are highlighted in this slide.

6   That is a method of increasing blood pressure in a patient

7   who needed it. That would be a hypotensive patient. And

8   always within a specific standard dosage range of anywhere

9   between 0.01 units per minute to a high of 0.1 unit per

10   minute by continuous IV infusion.

11   Q.   Okay. Move on to slide 11. Doctor, did you hear Dr.

12   Park provide a definition of POSA?

13   A.   I did.

14   Q.   And what is that definition?

15   A.   The definition is defined adequately on the screen,

16   and this is the definition that I used throughout my

17   analysis of all of the data.

18   Q.   And how does your analysis in this case relate to this

19   definition?

20   A.   Well, I would be a clinician with whom a POSA would

21   collaborate and work with.

22   Q.   Let's now jump back to the original Vasostrict label.

23   We're moving to slide 12.

24   How does a description of use of the -- let me

25   start again. How does the description of use of original

Cross - direct

1   Vasostrict as provided in the label compare to the clinical

2   elements of the '209 patent?

3   A.   We could see that the original Vasostrict label

4   teaches the '209 patent's clinical elements.

5   Q.   And more specifically, how did the indications and the

6   dosages provided in the Vasostrict label compare to the

7   clinical elements?

8   A.   On the left-hand side of the screen, you could see the

9   indication for Vasostrict being used as a method to increase

10 blood pressure for distributive or vasodilatory shock states

11 and that means in patients who are hypotensive. They also

12 give on the left-hand side specific dosage ranges as we had

13 just mentioned that all fall within the standard widely

14 accepted dosage range of anywhere between 0.01 units per

15 minute to a ceiling of 0.1 units per minute if by continuous

16 IV infusion.

17 Q.   Now, would a clinician that would work with a POSA

18 rely on this label for guidance on how to use original

19 Vasostrict?

20 A.   Definitely.

21 Q.   Now take a look at slide 13. I would like to switch

22 gears a little bit and now talk about the 2014 label for

23 Vasostrict in connection with Eagle and Amneal's inequitable

24 conduct case.

25   Now, let's start with the '239 patent. Do you

Cross - direct

1   understand how the '239 patent is related to the

2   patents-in-suit?

3   A.   Yes.   I was informed that the '239 patent is a parent

4   patent of the patents-in-suit.

5   Q.   And this slide identifies excerpts from pages 13 of

6   PTX-36.   What is PTX-36?

7   A.   PTX-36 is the April 2014 Vasostrict label.

8   Q.   And how does the description of use provided in the

9   April 2014 Vasostrict label compare to the clinical elements

10   of the '239 patent?

11   A.   The April 2014 Vasostrict label again teaches each of

12   the clinical elements of the '239 patent.

13   Q.   More specifically, how do the indications, the

14   dilution step, and the dosages as provided in the April 2014

15   Vasostrict label compare to the clinical elements of the

16   '239 patent?

17   A.   They are the same.   On the left-hand side, once again,

18   we see Vasostrict being used as a method to increase blood

19   pressure in patients who were hypotensive.   Also, the

20   dilution steps that are noted in 2.1 are the same as the

21   dilution steps of the '239 patent.   We can see the range of

22   0.1 unit per ml as the low dilution and one unit per ml as

23   the high dilution, the same as the '239 patent.

24   And on the bottom of the left side of the

25   screen, once again, we see the specific dosage ranges

1   recommended for post-cardiotomy shock and septic shock all

2   falling within the standardized dosage range noted in the

3   '239 patent, and that is, once again, 0.01 unit per minute

4   to the ceiling of 0.1 unit per minute by IV infusion.

5   Q.   Okay. Now we're on slide 14. Now let's now turn back

6   to the '209 patent.

7   How does the description of use as provided in

8   the April 2014 Vasostrict label compare to the clinical

9   elements of the '209 patent?

10   A.   The April 2014 Vasostrict label teaches each of the

11   elements of the '209 patent.

12   Q.   And, more specifically, how do the indications and

13   dosages as provided in the April 24th Vasostrict label

14   compare to the clinical elements of the '209 patent?

15   A.   They are the same. On the left I repeat Vasostrict

16   being used to increase blood pressure in patients with

17   distributive shock who, of course, would be hypotensive.

18   And, again, the recommended doses for both cardiotomy shock

19   and for septic shock are listed with their low and high

20   ranges, again all falling within the standardized dosage

21   range widely accepted for the previous 45 years of

22   0.01 units per minute to the high of 0.1 unit per minute by

23   IV infusion.

24   Q.   Thank you, Doctor. My colleague just pointed out that

25   I may have asked a question without actually referring to

Cross - direct

1   the claims of the '209 patent, so let me re-ask that.

2   A.   Certainly.

3   Q.   How does the description of use as provided in the

4   2014 Vasostrict label in terms of indications and dosages

5   compare to the clinical elements, clinical claim elements of

6   the '209 patent that are provided on the right side of the

7   screen?

8   A.   Yes. The April 2014 Vasostrict label teaches each of

9   the clinical elements of the '209 patent.

10   MR. KWON: No further questions.

11   THE COURT: Mr. Rhoad?

12   BY MR. RHOAD:

13   Q.   Good afternoon, Dr. Cross. My name is Bob Rhoad.

14   Nice to meet you.

15   A.   Good afternoon, Bob.

16   Q.   Jumping ahead of the binders. Let me get you some

17   binders. We got your name wrong, too, apparently on the

18   slide. We brought up the wrong person. There we go.

19   Now, Dr. Cross, based on your experience, if the

20   FDA were to approve Eagle's ANDA, you would expect that

21   clinicians like yourself would administer Eagle's product in

22   accordance with the instructions provided on the package

23   insert; right?

24   A.   Yes, I would.

25   Q.   And in particular, you would expect that clinicians

Cross - direct

1   would follow the instructions with respect to the dosage and

2   administration portions of the package insert; right?

3   A.   Yes.

4   Q.   And you agree that drug products can be used at any

5   time during their approved shelf life so long as they've

6   been stored properly; right?

7   A.   I do.

8   Q.   And do you understand that Vasostrict is typically

9   stored in refrigerated conditions?

10   A.   I understand so.

11   Q.   And you would expect that Eagle's product, if it were

12   to be approved, would also be stored in refrigerated

13   conditions?

14   MR. KWON: Objection, Your Honor. This is

15   outside of his report.

16   MR. RHOAD: I'm not allowed to ask questions

17   outside of his report?

18   MR. KWON: This is outside the scope of the

19   direct. The direct was related to obviousness of the

20   clinical claim elements of the patent. Now, Par is asking

21   questions directed to infringement.

22   THE COURT: All right. Hold on. My computer

23   froze. I was actually trying to figure out what's going on.

24   I need to pull up the live transcript.

25   MR. RHOAD: I will save us time, Your Honor. I

1   will withdraw the question.

2   THE COURT: I still want to pull this up, but go

3   ahead.

4   BY MR. RHOAD:

5   Q.   Now, you actually prepared and served two expert

6   reports in this case; right?

7   A.   Yes.

8   Q.   And in one of them was a rebuttal to Dr. Coralic's

9   infringement report; right?

10   A.   Yes.

11   Q.   And although in that report you provided rebuttal to

12   some of Dr. Coralic's opinions, you didn't rebut any of his

13   opinions in the report about the infringement of the '209

14   patent?

15   A.   That's correct.

16   Q.   Now, and you're not expressing any opinions here today

17   about the ultimate validity of any patent claims; right?

18   A.   With respect to clinical patent claims?

19   Q.   The ultimate obviousness of the patent claim as a

20   whole, you're not expressing those opinions, are you?

21   You're only talking about clinical limitations; right?

22   A.   Yes, that's correct.

23   Q.   And you understand that the claims also include

24   formulation related limitations like pH and impurities;

25   right?

Cross - direct

1   A.   I do, sir.

2   Q.   And you are not expressing any opinions about those?

3   A.   No, not at all.

4   Q.   So you are not expressing opinions about the ultimate

5   validity of the patent claims. You're just explaining what

6   you believe was disclosed with respect to some of the

7   limitations?

8   A.   That's correct.

9   Q.   And, in fact, you would lack the experience and

10   expertise to talk about the formulation-related elements

11   like pH and impurities; right?

12   A.   Yes.

13   Q.   And now you testified about that JHP and Par didn't

14   conduct any clinical studies relating to the NDA, in support

15   of the NDA that they filed for Vasostrict.

16   Do you recall that testimony?

17   A.   Yes, with respect to the clinical elements.

18   Q.   Right. And so you're certainly not suggesting that

19   Par or JHP didn't do a lot of work characterizing the

20   impurities and studying impurities and doing stability

21   studies on a product and things like that; right?

22   A.   No.

23   Q.   Now, I just want to make sure we're all on the same

24   page as to exactly what the clinical limitations you're

25   talking about are, so I've pulled up PDX-5-2.

1   So this is claim 1 of the '209 patent and we've

2   highlighted what you are referring to as the clinical

3   limitations; correct?

4   A.   Correct.

5   Q.   And the ones that aren't highlighted, those are

6   the formulation related limitations you are not talking

7   about?

8   A.   That's true.

9   Q.   The '239 patent, here again, this is claim 1 of the

10   '239 patent, and we've highlighted in yellow what you're

11   referring to as the clinical limitations that you are

12   testifying about and they're highlighted in yellow; right?

13   A.   That's true.

14   Q.   And the ones that aren't -- the limitations that are

15   not highlighted here are the formulation related limitations

16   of the '239 patent that you are not testifying about; right?

17   A.   Also true.

18   Q.   All right. I would like to now pull up paragraph 39

19   of your report, which is shown here on PDX-5-4, and by the

20   way, the '239 slide was PDX-5-3.

21   So this is paragraph 39 of your report. And

22   this is where you give a list of all of the clinical

23   limitations that you identified in your report and that you

24   expressed opinions about; right?

25   A.   Yes. The common clinical elements, yes.

Cross - direct

1   Q.   And so when you in your report are talking about,

2   quote unquote, the clinical limitations, you're talking

3   about this list of limitations that you provided in

4   paragraph 39 of your report; is that correct?

5   A.   Yes.

6   Q.   And your testimony is that clinicians used Vasopressin

7   products in accordance with all of these clinical

8   limitations before Par filed for its patents. Is that your

9   testimony?

10   A.   Yes.

11   Q.   And your opinion is that all of these clinical

12   limitations were taught in the scientific literature that

13   was published before Par's patent. Is that your testimony?

14   A.   That's also true, sir.

15   Q.   And your belief is that each of these clinical

16   limitations was taught by the April 2014 Vasostrict --

17   strike that. Your testimony -- your opinion is that each of

18   the clinical instructions that are provided on the

19   April 2014 label were taken directly from earlier prior art;

20   is that right?

21   A.   That's true.

22   Q.   And your testimony is that each of the clinical

23   limitations that are taught by the April 2014 label merely

24   recite what you say was long known and practiced in the

25   prior art; right?

Cross - direct

1   A.   True.

2   Q.   Now, during the course of your work in this case, you

3   reviewed the prosecution histories from the '239 and '209

4   patents; is that correct?

5   A.   I did.

6   Q.   And your review revealed that the Examiner agreed with

7   you about the testimony you've provided here, that all of

8   the clinical limitations of these patents were taught by the

9   prior art; right?

10   A.   Yes.

11   Q.   And those findings, Par never attempted to rebut those

12   findings by the Examiner; is that correct?

13   A.   That's correct.

14   Q.   And the Examiner allowed the patents to issue not

15   because of any differences between the claims and the prior

16   art relating to the clinical limitations, but based instead

17   on other arguments; right?

18   A.   That is what I understand.

19   Q.   And you agree with the Examiner about what the prior

20   art disclosed about those clinical limitations; right?

21   A.   I do.

22   Q.   So with that in mind, let's go back to claim 1 of

23   the '209 patent.

24   So the Patent Examiner found that each of the

25   clinical limitations highlighted here on PDX-5-2 from

Cross - direct

 1   claim 1 of the '209 patent was disclosed in the prior art;

 2   right?

 3   A.   Yes.

 4   Q.   And, in particular, she found that they were disclosed

 5   by Tanja Treschan and Russell references; right?

 6   A.   Yes.   Tanja Treschan and James Russell for sure.

 7   Q.   So please take a look at PTX-238 in your binder.

 8   A.   PTX-238, yes.

 9   Q.   That's a copy of the Treschan reference; right?

10   A.   This is one of Tanja Treschan's articles, yes.

11   Q.   This is the one that you relied upon in your report

12   as, this is the one that was cited by the Examiner during

13   the prosecution of the patents?

14   A.   Yes.

15   Q.   The '209 and '239 patents?

16   A.   Yes.   This is the article I believe that the Examiner

17   cited.

18   Q.   And the Treschan and Russell references were prominent

19   references in the field as it comes to the -- whether it

20   comes to the use of Vasopressin; right?

21   A.   Certainly.

22   Q.   All right.   And I think I may have misspoke.   Am I

23   correct that the Treschan reference that we just looked at

24   was DTX-238, not PTX-238?

25   A.   It's "D," David.

Cross - direct

1   Q.   Thank you. And I apologize for that misspeaking.

2   Now, and so the Examiner allowed the '209 patent

3   to issue based on arguments relating to the pH of the

4   claimed formulation, not because of any of the clinical

5   limitations; right?

6   A.   As I understand it, yes.

7   Q.   All right. Let's take a look at the '239 patent

8   that's shown on PDX-5-3 with highlighting.

9   So the Patent Examiner found that each of the

10   clinical limitations highlighted here that you've been

11   testifying about was disclosed in the prior art; is that

12   correct?

13   A.   That is correct.

14   Q.   And, in particular, she found that these limitations,

15   again, were taught by the Treschan and Russell references;

16   right?

17   A.   Yes. Treschan and Russell and Young.

18   Q.   So a number of references?

19   A.   Certainly.

20   Q.   And the Examiner allowed the '239 patent to issue for

21   reasons other than the differences between the clinical

22   elements of the claim and the prior art; right?

23   A.   That is true.

24   Q.   All right. Let's go back to your list of all of the

25   clinical limitations and that's again on PDX-5-4.

1   And the Examiner found that all of these

2   limitations were known and practiced before Par's patent;

3   right?

4   A.   I certainly found all of these limitations as having

5   existed in prior art.   I'm not sure she enumerated each one

6   of these.

7   Q.   Let's talk about a couple of them.   So the Examiner

8   understood and believed that Par did not invent intravenous

9   administration of Vasopressin; right?

10   A.   True.

11   Q.   And the Examiner understood and believed that Par did

12   not invent --

13   MR. KWON: Objection, Your Honor.   These are

14   questions going to the state of mind of the Examiner.   I

15   think these questions should be rephrased.

16   MR. RHOAD: Your Honor, he reviewed -- he has

17   reviewed the prosecution histories.   He has testified about

18   what the Examiner knew and understood at the time, and, in

19   fact, in his report, he had a whole section entitled

20   Examiner confirmed my opinions about the prior art, or

21   something along those lines.

22   THE COURT: Let me see counsel at sidebar.

23   (Sidebar conference held as follows.)

24   MR. RHOAD: So it goes to the issue of

25   inequitable conduct and materiality and intent to deceive.

1   So they've alleged that, for example -- they've

2   elected, for example, that Mr. Kannan made a false

3   declaration when he said, I invented the subject matter of

4   this claim.

5   And, you know, Dr. Kannan was outside. I

6   invented storage, refrigerated storage and I certainly

7   didn't intend to suggest I invented, you know, the use of

8   Vasopressin for intravenous. And we just want to establish

9   there's no materiality here. The Examiner understood all of

10   that. In fact, she found it all disclosed.

11   THE COURT: Right.

12   MR. RHOAD: There's no materiality here.

13   MR. KWON: A couple rebuttal. First off, we

14   don't agree with the description of false declarations at

15   all, but beside that, we have no objections to this line of

16   questions.

17   Our objection was directed to how the question

18   was phrased. The question was the Examiner understood, the

19   Examiner understood this was already in the art. Right.

20   This was going to the state of mind of the Examiner, so we

21   thought we could rephrase the question. We have no issue

22   with this topic.

23   MR. RHOAD: Based on his review of the

24   prosecution history, where the Examiner said what she was

25   finding and what she believed the prior art to disclose.

1   MR. KWON: I just --

2   THE COURT: I will tell you what. What's good

3   for the good for the goose is good for the gander. It's a

4   fine line. I mean, why don't you just --

5   MR. RHOAD: Ask what the Patent Examiner found?

6   THE COURT: Yes. Found or recognized or stated.

7   MR. RHOAD: Okay.

8   THE COURT: I just take out the word understand.

9   Especially given that Mr. Black had objected to the prior

10 statement, it would be consistent.

11   (End of sidebar conference.)

12 BY MR. RHOAD:

13 Q.   Okay. So, Dr. Cross, you would agree that the

14 Examiner recognized that Par did not invent the use of

15 Vasopressin to treat intravenous administration, to treat

16 patients using Vasopressin by intravenous administration;

17 right?

18 A.   That's correct.

19 Q.   And you understand that the Examiner recognized that

20 Par did not invent the use of Vasopressin to treat patients

21 who are hypotensive; right?

22 A.   That is also correct.

23 Q.   And you understand that the Examiner recognized that

24 Par did not invent the use of Vasopressin to treat patients

25 suffering from vasodilatory shock?

1   A.   Also true.

2   Q.   And you understand that the Examiner recognized that

3   Par did not invent treating post-cardiotomy shock with a

4   starting dose of 0.03 units per minute; right?

5   A.   Also true.

6   Q.   And you understand that the Examiner recognized that

7   Par did not invent treating septic shock with a starting

8   dose of 0.01 units per minute?

9   A.   Yes.

10 Q.   All right. Let's take a look, please, if you would,

11 at PTX-1440.

12 A.   "P" like Peter; right?

13 Q.   Correct. Are you there?

14 A.   Yes.

15 Q.   Do you recognize this as an office action that was --

16 that issued in the course of the prosecution of Application

17 Number 14717877?

18 A.   Yes.

19 Q.   Do you see the notification date on the first page of

20 January 11, 2016?

21 A.   Yes, I do.

22 Q.   Okay. Now, do you see on page 4 of Exhibit PTX-1440,

23 that's where the Examiner is making certain findings, for

24 example, with regard to Treschan?

25 A.   Yes.

1   Q.   And this is an example of the type of office action

2   that you reviewed and relied upon for your testimony that

3   you have given about what the Examiner recognized?

4   A.   Yes.

5   Q.   Now, you agree that the prior art references that were

6   before the Examiner during prosecution of the '209 and '239

7   patents contain the same teachings with respect to the

8   clinical limitations of those patents as the April 14, 2014,

9   Vasostrict label; right?

10   A.   Yes.

11   Q.   And the Examiner was also aware during prosecution of

12   these patents about the clinical uses of Pitressin; right?

13   A.   Can you please repeat that?

14   Q.   The Examiner was aware of the clinical uses of

15   Pitressin during the course of the prosecution of these

16   patents; right?

17   A.   Yes.

18   Q.   And from your perspective, any information with

19   respect to Pitressin that was material to the pending patent

20   claims was before the Examiner during prosecution; right?

21   A.   You are referring to clinical?

22   Q.   With respect to clinical limitations?

23   A.   Yes.

24   MR. RHOAD: No further questions. I pass the

25   witness, but I would move to introduce into the record

Cross - direct

1   PTX-1440 and DTX-238, the Treschan reference.

2   THE COURT: Okay.

3   MR. KWON: Your Honor, no redirect from

4   defendants, but we would like to move to admit exhibits.

5   THE COURT: Well, hold on. Do you object to the

6   admission?

7   MR. KWON: No objection. No objection, Your

8   Honor.

9   THE COURT: All right. They are admitted.

10   I've got to tell you, Mr. Rhoad, this is an

11   example where I feel like I'm going out on thin ice here,

12   that we're going to introduce an article where there has

13   been no discussion of the contents of the article. So just

14   keep in mind under my rule, neither side is going to get to

15   talk about this Treschan article unless there was testimony

16   elicited about the subject matter. This is exactly what

17   I'm --

18   MR. RHOAD: Your Honor --

19   THE COURT: I am not saying you intend to do

20   that at all.

21   MR. RHOAD: The reason I introduced it for the

22   record, the Examiner relied on it and in 1440 cited

23   provisions for it.

24   THE COURT: Right.

25   MR. RHOAD: I just want to have in the record

Cross - direct

1   the reference that the Examiner was talking about and

2   referencing during the course --

3   THE COURT: That's fair. What I don't want is

4   if you were going to go in post-trial briefing and say, so

5   the Examiner relied on it and here's what it said, this

6   is all the important stuff, I just think there has to be

7   some --

8   MR. RHOAD: I don't think we'll be pointing to

9   anything besides what the Examiner herself pointed to in the

10   exhibit that was just admitted into evidence and I'm not

11   admitting it for any other purpose.

12   THE COURT: Okay. All right. Then it's

13   admitted.

14   (Exhibits admitted into evidence.)

15   THE COURT: All right. Mr. Kwon, you had some

16   exhibits you wanted admitted?

17   MR. KWON: Yes, Your Honor. Defendants would

18   like move to admit Exhibits DTX-36, DTX-246, DTX-178,

19   DTX-249, DTX-25, DTX-42 and DTX-132.

20   THE COURT: All right. Any objection?

21   MR. RHOAD: No objection, Your Honor.

22   THE COURT: All right. They are all admitted.

23   MR. KWON: Thank you.

24   (DTX-36, DTX-246, DTX-178, DTX-249, DTX-25,

25   DTX-42 and DTX-132 were admitted into evidence.)

1   THE COURT: What's next? You may step down.

2   Thank you very much.

3   THE WITNESS: Thank you.

4   (Witness excused.)

5   MR. HALES: Your Honor, we now have a series of

6   video depositions to play.

7   THE COURT: Okay.

8   MR. HALES: And this is a series of, as I

9   mentioned in opening, I think of unavailable witnesses.

10   THE COURT: Oh, this is the inequitable conduct

11   case?

12   MR. HALES: Well, there's a series of them.

13   It's not all inequitable conduct, but those are coming.

14   The first one we're going to play is Inventor

15   Kannan.

16   THE COURT: All right.

17   MR. HALES: That will be one. We have a few

18   more.

19   THE COURT: Okay.

20   MR. HALES: Your Honor, this has per protocol,

21   the integration of the clips designated by both parties.

22   The time for defendants is 22 minutes, 51 seconds. Time for

23   plaintiff, 18 minutes, 03 seconds. You'd better restart.

24   No audio.

25   (The videotaped deposition of Vinayagam Kannan

1   was played as follows.)

2   "Question: Could you please state your full

3   name for the record?

4   "Answer: My full name is Vinayagam Kannan.

5   "Question: And it would have been December 2012

6   that you started working with JHP; is that correct?

7   "Answer: That is correct.

8   "Question: And what was the purpose for which

9   you were comparing the attributes of JHP's Vasopressin

10   product and other unapproved Vasopressin products?

11   "Answer: The product was, at that time, I was

12   asked to look at because there was an issue when the product

13   was diluted with sodium chlorate and dextrose. They were

14   having an issue that the potency was declining when it was

15   diluted with dextrose. So I was asked to make a comparison

16   and try to help troubleshoot. I was working with Mike

17   Bergren and helping him with my analysis.

18   "Question: So after the project to investigate

19   dilution of the formulation of Vasopressin in dextrose, the

20   next project you worked on was under the direction of Suketu

21   Sanghvi; is that right?

22   "Answer: That's my recollection. There may be

23   some activity happen in between.

24   "Question: So you said the project was related

25   to filing of something for refrigerated product?

Kannan - designations

1   "Answer: Okay. PAS. That is the prior

2 approval supplement.

3   "Question: Okay. Got it.

4   "And why was Par looking to file a PAS for a

5 refrigerated product?

6   "Answer: My recollection is at that time, the

7 original approval was for 12-month shelf life with room

8 temperature, so Par was looking to file refrigerated

9 product.

10   "Question: And later you were involved in a

11 project to reformulate that original Vasostrict formulation,

12 correct?

13   "Answer: In between I was also involved in

14 converting that original Vasostrict product into

15 refrigerated product.

16   "Question: When you say you were involved in

17 converting the original Vasostrict product into a

18 refrigerated product, is that something different from your

19 work in reformulating the product?

20   "Answer: That is correct, that is different.

21   "Question: What was involved in the project to

22 convert the original Vasostrict formulation into a

23 refrigerated product?

24   "Answer: I think I answered to this question

25 before. I worked with Matt Kenney. We evaluated the data.

1   We did statistical analysis of what -- whatever need to be

2   done for the submission.

3   "Question: My question is whether you had any

4   role in determining the indications and usage for Vasostrict

5   as reflected in the label.

6   "Answer: No, I did not.

7   "Question: Okay. And then if we look at the

8   dosage and administration section of the approved -- or the

9   label attached to the April 24th approval letter, did you

10   have any role in determining the dosage and administration

11   for the Vasostrict as reflected in the label?

12   "Answer: As I described earlier to another

13   question, I was involved in evaluating compatibility of

14   Vasopressin injection with sodium chloride and five percent

15   dextrose. The label was updated after that.

16   "Question: Okay. So April 2014, the approval

17   is given with a 12-month room temperature shelf life, and

18   then later that year in September 2014, a 24 months at two

19   to eight degrees Celsius shelf life is given; is that your

20   understanding?

21   "Answer: My understanding is around September

22   time frame had 24-month shelf life at 2 to 8 degrees C.

23   "Question: Do you know what was done to support

24   the change between the April 2014 label with a 12-month room

25   temperature shelf life and the later label with a 24-month

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1   refrigerated shelf life?

2   "Answer: My recollection is that it was a prior

3   approval supplement filed with FDA.

4   "Question: Okay. Were you involved in the work

5   that led to that prior approval supplement?

6   "Answer: Yes. I was involved with my

7   co-worker, Matt Kenney, in evaluating all the data and

8   making recommendations on what the shelf life would be if we

9   store at 2 to 8 degrees C.

10   "Question: Okay. And that is different from

11   the later supplement to seek an out-of-refrigerated time; is

12   that right?

13   "Answer: I do not recollect if that is a

14   later -- that later submission was a supplement or some

15   other type of filing. My recollection is that we amended

16   further to add out-of-refrigeration time of 12 months.

17   "Question: Between two Vasopressin formulations

18   with identical shelf lives, are you aware of any clinical or

19   other advantage for a product that has less impurities

20   within the specifications?

21   "Answer: I am not aware.

22   "Question: Okay. And between two Vasopressin

23   formulations with identical shelf lives, are you aware of

24   any clinical or other advantage for a product that has a

25   higher assay value within the specifications?

 1   "Answer: I am not.

 2   "Question: And ultimately, as far as you know,

 3   the shelf life for the new formulation was not, in fact,

 4   improved over the shelf life of the original Vasostrict

 5   formulation, correct?

 6   "Answer: As far as I know, we have data that is

 7   supporting at least 18 months stability when I was at Par.

 8   The part that I don't know is that whether that was actually

 9   filed with the FDA seeking approval.

10   "Question: I'm handing you a document marked

11   Exhibit 30. And it's a response to the office action in the

12   prosecution of Application No. 14/717,877.

13   "Do you see that?

14   "Answer: Yes.

15   "Question: And that is a patent on which, the

16   patent application on which you were a named inventor; is

17   that correct?

18   "Answer: Yes.

19   "Question: Okay. And if you look at the claims

20   that are being proposed at the time, that's on page 3 of the

21   document.

22   "Do you see that?

23   "Answer: Yes.

24   "Question: Okay. And so there's a claim 16

25   which describes a method of increasing blood pressure in a

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1   human in need thereof the method comprising.

2   "Do you see that?

3   "Answer: Yes.

4   "Question: And then it talks about providing a

5   particular pharmaceutical composition with certain

6   attributes, right?

7   "Answer: Yes.

8   "Question: Then it talks about storing the unit

9   dosage form from 2 to 8 degrees Celsius; right?

10   "Answer: Yes.

11   "Question: And then administering the unit

12   dosage form to a human, given certain amounts of

13   Vasopressin; correct?

14   "Answer: Correct.

15   "Question: And the human is hypotensive, right,

16   in that claim?

17   "Answer: Correct.

18   "Question: I handed you a document marked

19   Exhibit 31. It is an office action, and the notification

20   date is October 21, 2015.

21   "Do you see that?

22   "Answer: I see that.

23   "Question: And this is, again, in the

24   prosecution of Application Number 14/717,877.

25   "Do you see that?

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1   "Answer: I see that.

2   "Question: And the Examiner is Christina

3   Bradley?

4   "Do you see that?

5   "Answer: I see that.

6   "Question: Okay. And then if you look at page

7   3 of the document, you'll see that certain claims of the

8   application are rejected as anticipated by or in the

9   alternative as obvious over the FDA label for Vasostrict

10   published April 2014.

11   "Do you see that?

12   "Answer: I see that.

13   "Question: And then the Examiner goes on to say

14   what the FDA label teaches.

15   "Do you see that?

16   "Answer: I see that.

17   "Question: And then the Examiner goes on, on

18   page four to explain how the label describes limitations of

19   other claims.

20   Do you see that?

21   "Answer: I see.

22   "Question: I've handed you what is being marked

23   as Exhibit 32. Exhibit 32 is a copy of the April 2014

24   Vasostrict label taken from the prosecution history of

25   application number 14/717,877.

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1   "Do you recognize this document?

2   "Answer: Yes.

3   "Question: And this is the same Vasostrict

4   label that was approved by the FDA when they approved the

5   original formulation of Vasostrict in April 2014, correct?

6   "Answer: Correct.

7   "Question: If you can keep Exhibit 32 handy,

8   but I'm handing you what's being marked as Exhibit 33.

9   "And Exhibit 33 is a response to final office

10   action and request for continued examination, also in

11   prosecution of application number 14/717,877, electronically

12   filed on November 24, 2015.

13   "Do you see that?

14   "Answer: Yes.

15   "Question: Okay. And then if we look on page 6

16   of Exhibit 33, you'll see towards the top the statement is

17   made that "Applicant submits that the label is not prior art

18   because the label was disclosed less than one year prior to

19   the effective filing date by another who obtained the

20   disclosed subject matter directly or indirectly from the

21   joint inventors."

22   "Do you see that?

23   "Answer: I see that.

24   "Question: If you go -- stay on the same page 6

25   of Exhibit 33. You'll see there's an explanation as to why

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1   Par was claiming that the disclosure was made by another who

2   obtained the subject matter disclosed directly or indirectly

3   from the inventor or a joint inventor.

4   "Do you see that?

5   "Answer: I see that.

6   "Question: And one of the bases for that

7   statement is a declaration from you, correct?

8   "Answer: Correct.

9   "Question: And on page 7, the second to last

10   paragraph, you see there it states, "As described by

11   Vinayagam Kannan, the label discloses part of the subject

12   matter of the claims, including a method of increasing blood

13   pressure in a hypertensive human.

14   "Do you see that?

15   "Answer: I see that.

16   "Question: And then it goes on to describe some

17   of the information in the label.

18   "Do you see that?

19   "Answer: I see that.

20   "Question: And then it says, Kannan states that

21   the FDA obtained this information from v. Kannan and Matthew

22   Kenney as they invented this subject matter.

23   "Do you see that?

24   "Answer: I see that.

25   "Question: And for that statement, it's relying

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1   on paragraph 7 of your declaration, correct?

2   "Answer: Correct.

3   "Question: I'm handing you what's been marked

4   as Exhibit 34. Is this the declaration that you submitted

5   during prosecution of the application number 14/717,877

6   that's being referred to in the office action Exhibit 33?

7   "Answer: Yes.

8   "Question: Okay. And in paragraph 4, you state

9   that you've reviewed the final office action, correct?

10   "Answer: Correct.

11   "Question: And then you include a section in

12   your declaration titled, 'The label recites subject matter

13   that the FDA obtained either directly or indirectly from

14   joint inventors of the '877 application.'

15   "Do you see that?

16   "Answer: I see that.

17   "Question: Okay. And if we look down, you

18   describe what the label discloses in paragraph 7.

19   "Do you see that?

20   "Answer: I see that.

21   "Question: Okay. And you say -- and at the end

22   of that paragraph, you say, 'The FDA obtained this

23   information from me and Matt Kenney as we invented this

24   subject matter.'

25   "Do you see that?

1   "Answer: I see that.

2   "Question: Right. And you provided the

3 declaration in response to the Examiner's rejection in order

4 to convince the Examiner to withdraw the rejection of your

5 claims over the April 2014 Vasostrict label and grant you a

6 patent, correct?

7   "Answer: Correct.

8   "Question: Did you work with anyone to put

9 together this declaration?

10   "Answer: The declaration was drafted by the

11 legal department.

12   "Question: The internal Par legal department?

13   "Answer: Internal Par legal department.

14   "Question: Okay. If we go to paragraph 7 of

15 your declaration, Exhibit 34. You state, 'The label

16 discloses part of the subject matter of the claims including

17 a method of increasing blood pressure in a hypotensive

18 human. The label recites that Vasostrict is indicated to

19 increase blood pressure in adults when vasodilatory shock

20 who remain hypertensive.'

21   "Stopping there. You did not invent the method

22 to increase blood pressure in adults with vasodilatory shock

23 who remain hypotensive as described in the label, correct?

24   "Answer: That is correct, I did not invent.

25   "Question: Now, the label describes a

1   pharmaceutical composition for intravenous administration

2   having 20 units of Vasopressin per ml.

3   "Do you see that?

4   "Answer: I see that.

5   "Question: And if you need to refer to the

6   label in Exhibit 32, you can. The formulation is described

7   on page 6 in Section 11.

8   "Do you see that?

9   "Answer: Yes, I see that.

10   "Question: And, again, you did not invent that

11   formulation described in section 11 on page 6 of the

12   April 2014 Vasostrict label, right?

13   "Answer: Correct.

14   "Question: And your declaration goes on to

15   state, 'The label further recites that the Vasopressin

16   formulation comprises chlorobutanol and water for injection,

17   USP adjusted with acetic acid to pH 3.4 to 3.6.'

18   "Do you see that?

19   "Answer: I see that.

20   "Question: And that is part of the formulation

21   described in the label, Exhibit 32, that you did not invent,

22   correct?

23   "Answer: Correct.

24   "Question: The paragraph 7 of your declaration,

25   Exhibit 34, goes on to state, 'The label recites the

1   infusion rate of the claim by stating that for post

2   cardiotomy shock, start with a dose of 0.03 units per ml --

3   per minute,' excuse me, for septic shots, start with a dose

4   of 0.01 units per minute.

5   "Do you see that?

6   "Answer: I see that.

7   "Question: And you didn't invent that subject

8   matter either, correct?

9   "Answer: Correct.

10   "Question: Okay. Then it states, the label

11   recites refrigeration of the diluted Vasopressin for up to

12   24 hours.

13   "Did you invent that subject matter?

14   "Answer: I may have contributed to that

15   subject.

16   "Question: The FDA, we saw earlier, suggested

17   refrigerating the Vasostrict formulation, correct?

18   "Answer: Based on the document we reviewed

19   earlier.

20   "Question: Right. And so you did not invent

21   the idea of refrigerating diluted Vasopressin, correct?

22   "Answer: What I am trying to say, I contributed

23   in evaluating that refrigeration of diluted Vasopressin.

24   "Question: How did you contribute to that?

25   "Answer: Early on when I started at JHP

1   pharmaceuticals, if you recall, we were trying to address

2   the issue of loss in potency with dextrose injection.

3   "Question: Right.

4   "Answer: And diluted, so...

5   "Question: Right. And that you didn't invent

6   the idea of refrigerating a Vasopressin formulation for

7   24 hours after dilution, correct?

8   "Answer: That 24 hours, it is described here,

9   it was based on the data generated at that time.

10   "Question: In what way was it based on that

11   data?

12   "Answer: Could you please clarify your

13   question?

14   "Question: Yes. How was the statement in the

15   label for refrigeration of the diluted Vasopressin for up to

16   24 hours based on data that you prepared?

17   "Answer: I don't know how it is based on the

18   data that I prepared. I am saying I contributed to that

19   evaluation.

20   "Question: That evaluation was related to

21   dextrose in a diluted formulation, correct?

22   "Answer: Correct.

23   "Question: It wasn't related to testing amounts

24   of refrigeration of a diluted formulation, right?

25   "Answer: It was also related to study and

1   testing of diluted formulation.

2   "Question: In what way?

3   "Answer: The label claim is based on the data

4   generated at that time.

5   "Question: So it's your testimony today, sir,

6   that of all of the information that is provided in paragraph

7   7 of your declaration, you contributed in some way only to

8   the claim for refrigeration of diluted Vasopressin for up to

9   24 hours, right?

10   "Answer: That is correct. I would also like to

11   clarify that for the claims related to this patent

12   application, my major contribution is towards refrigerated

13   storage at 2 to 8 degrees C for the final product.

14   "Question: Under penalty of perjury, you told

15   the Patent Office that you and Matthew Kenney contributed

16   all of the subject matter in paragraph 7, correct?

17   "Answer: As it states here, that the

18   information was taken from me and Matt Kenney.

19   "Question: Right. As you invented this subject

20   matter, right, that's what you told the Patent Office.

21   Correct?

22   "Answer: I see that it states here.

23   "Question: Right. And that this subject matter

24   is referring to the subject matter earlier in the paragraph

25   7; correct?

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1   "Answer: I would like to clarify again for the

2   record my contribution to the claims in this particular

3   patents were related to refrigerated storage at 2 to 8

4   degrees C. I did not invent other claims related to --

5   related to composition or how it is administered.

6   "Question: Right. And so your statement that

7   you and Matthew Kenney invented all the subject matter in

8   paragraph 7 of your declaration, Exhibit 34, was false;

9   right?

10   "Answer: I am not sure if this is meant to say

11   that we invented all of the subject matter in the claims.

12   "Question: That's what it says, though. That's

13   how it reads; right?

14   "Answer: As I mentioned before, my contribution

15   was related to refrigerated storage. And as it states in

16   the document, we invented the subject matter.

17   "Question: I'm handing you what has been marked

18   as Exhibit 35. It's a copy of an office action dated

19   January 11, 2016.

20   "Do you see that?

21   "Answer: I see it.

22   "Question: And it's responsive to a

23   communication on November 24, 2015.

24   Do you see that? On the second page, you can

25   see that.

1   "Question: Do you see on page 2 of the

2   document, there's discussion of withdrawn rejections. Do

3   you see that?

4   "Answer: Yes.

5   "Question: And the Examiner withdraws the

6   rejection over the April 24th Vasostrict label?

7   "Do you see that?

8   "Answer: Yes.

9   "Question: And the Examiner states that 'The

10   declaration by inventor Vinayagam Kannan,' that's you,

11   correct?

12   "Answer: That's correct.

13   "Question: And that's referring to the

14   declaration we just looked at, Exhibit 34, correct?

15   "Answer: Correct.

16   "Question: So the declaration by inventor

17   Vinayagam Kannan includes an unequivocal statement that he

18   and Matthew Kenney invented the subject matter disclosed in

19   the FDA label and relied upon in the rejection.

20   "Do you see that?

21   "Answer: I see that.

22   "Question: Okay. And did you ever correct your

23   declaration to specify that you, as you say now, only meant

24   that you invented the subject matter of the refrigeration

25   conditions?

1   "Answer: I don't remember any further

2   communication happened after that.

3   "Question: Regardless of what you meant in

4   paragraph 7 of your declaration, Exhibit 34, it is not true

5   that you invented all the subject matter that's described in

6   paragraph 7 of your declaration, right?

7   "Answer: I would like to clarify again my

8   contribution related to refrigerated storage of the product.

9   "Question: Right. And none of the other

10   subject matter in paragraph 7 of your declaration,

11   Exhibit 34, right?

12   "Answer: That is correct.

13   "Question: Dr. Kannan, I'm handing you what has

14   been marked as Exhibit 36 to your deposition. It is a

15   document entitled 'Declaration under 37 C.F.R. Section 1.132

16   by Vinayagam Kannan, and it is filed in the Application

17   Number 14/717,882.'

18   "Do you see that?

19   "Answer: I see that.

20   "Question: And in this declaration, you are

21   analyzing data that was previously provided to the Patent

22   Office by Sunil Vandse, correct?

23   "Answer: Yes. I see it's stated here.

24   "Question: Okay. In paragraph 15 of your

25   declaration, Exhibit 36, you're describing the technique of

 1   normalization.

 2   "Do you see that?

 3   "Answer: Yes.

 4   "Question: And is normalization an important

 5   technique in comparative stability studies?

 6   "Answer: Normalization in this case would be

 7   applied because we had two different starting amounts of

 8   Vasopressin in two different studies. We wanted to compare

 9   the data, so we normalized as percent change in assay values

10   so we can get a direct comparison between two studies.

11   "Question: Okay. And then if you look in

12   paragraph 16, you state, 'As described above, because the

13   procedures for each of the experiments were the same, and

14   because pH was the only variable that was not normalized, I

15   conclude that the difference in the assay percent label

16   claim Vasopressin remaining and percent total impurities

17   results for each formulation were attributable to changes in

18   pH.'

19   "Do you see that?

20   "Answer: I see it.

21   "Question: Okay. So you told the Patent Office

22   that the only variable that was not normalized in the data

23   that was provided to them was pH, correct?

24   "Answer: This paragraph is referring to the

25   paragraph above. Can I read that paragraph --

1   "Question: Yes.

2   "Answer: -- before I answer your question?

3   "Counsel, this is referring to the paragraph

4   above which talks about normalization for percent decrease

5   in Vasopressin assay. In that context when we're looking at

6   assay data percent pH, assay data was normalized.

7   "Question: This sentence talks about three

8   variables, pH, assay and impurities; correct?

9   This is in paragraph 16 of your declaration,

10   Exhibit 36. Do you see that?

11   "Answer: Yes. I would like to clarify that the

12   total impurities data was not normalized, because it is not

13   impacted by the starting amounts of Vasopressin as a

14   percent.

15   "Question: Are you telling me that the starting

16   point of a test of impurity increase is not important?

17   "Answer: No. I would like to clarify again.

18   In this strategy related -- the studies discussed here,

19   there were two different studies.

20   "The only difference between those study was the

21   difference in the starting amount of assay. I don't recall

22   the numbers. One was started close to 100 percent and the

23   other was lower.

24   "When we were evaluating the data of absolute

25   amounts of Vasopressin or total impurities, total impurities

1   show a clear trend between pH values. Assay was not. So

2   this -- this response was related to a cushion why there is

3   a discrepancy between two data sets. Then we normalized the

4   data so that we are able to clearly see the trend for the

5   assay values.

6   "Question: You didn't normalize the data for

7   the impurities, right?

8   "Answer: We did not.

9   "Question: Well, rather, actually, you didn't

10   normalize them in the information provided to the Patent

11   Office, right?

12   "Answer: Yes. My understanding is that we did

13   not normalize impurities.

14   "Question: Right. So for this test, the test

15   of Vasopressin formulations between 2.5 and 4.5, by the time

16   you submitted your declaration to the Patent Office, you had

17   normalized data for impurities as well. Correct?

18   "Answer: I don't remember that.

19   "Question: You've been handed documents marked

20   Exhibits 37 through 39. Exhibit 37 is a document Bates

21   labeled Par-VASO-0034737. And it is an e-mail from yourself

22   to Matt Kenney.

23   "Do you see that?

24   "Answer: I see that.

25   "Question: And then you state, 'Please see if

1   these make sense. If yes, we can clean up and send to

2   Gina.'

3   "Do you see that?

4   "Answer: I see that.

5   "Question: Who was Gina that you were referring

6   to in Exhibit 37?

7   "Answer: Gina is from Legal.

8   "Question: Can you take a look, please, at

9   Exhibit 38. Exhibit 38 is a document bearing

10   Par-VASO-0034748.

11   "Do you see that?

12   "Answer: Yes.

13   "Question: And I will represent that this is

14   one of the attachments to the e-mail that is Exhibit 37,

15   okay?

16   "Does this plot, Exhibit 38, provide normalized

17   data for rate of change of impurities for the pH study you

18   conducted?

19   "Answer: It shows the rate of change of

20   impurities, so...

21   "Question: Okay. And that's using normalized

22   data for pH and impurities, correct?

23   "Answer: You normalize only the impurities data

24   and plot across the pH range.

25   "Question: I'm handing you what has been marked

1   as Exhibit 40 to your deposition. This is the declaration

2   of Sunil Vandse, and it's dated January 22, 2016.

3   "Do you see that?

4   "Answer: Yes.

5   "Question: If we look at Figure 1 of the

6   declaration on page 5. This is Sunil Vandse's declaration,

7   Exhibit 40. This is presenting percent total impurities

8   versus pH at the 25-degree temperature, correct?

9   "Answer: Correct.

10   "Question: And if we look between 3.3 and 3.4

11   and then down to 3.5 to 3.6, the data is presented as

12   showing a steep drop in impurities; correct?

13   "Answer: Between 3.4 and 3.5?

14   "Question. Correct.

15   "Answer: Is that your question, counsel?

16   "Question: Yes.

17   Answer: That's where the data points are, yes.

18   "Question: So for 25 degrees that we see in

19   Figure 1 of Sunil Vandse's declaration, the break in total

20   impurities between 3.4 to 3.5 is due to the fact that the

21   starting material had more than twice the amount of

22   impurities than for the two point -- for the 3.5 to 4.5

23   study, correct?

24   "Answer: I'm not able to conclude one way or

25   the other based on 25-degree C data alone. I would like to

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1   see the 40 degrees C data also.

2   "Question: So my question is only about the

3   25-degree data and the break between the values for the

4   total impurities for the 3.4 and the break in the impurities

5   for the 3.5. Can we focus on that?

6   "Answer: Yes, we can focus on that. What I'm

7   trying to say is the extent of change at 25 degrees C will

8   not be significant to see difference across the pH range.

9   That's the reason why I'm saying we would have to look at

10   the 40 degrees C data also to make that conclusion.

11   "Question: That's fine. I'm just trying to

12   understand the reason for the break between the data point

13   for total impurities at 3.4 at 25 degrees C and the data

14   point for total impurities at 3.5 at 25-degree C. So I want

15   to focus on that.

16   "Answer: Yes.

17   "Question: So if we look at the starting total

18   impurities at 3.4, there were 1.75 percent at initial?

19   "Answer: Correct.

20   "Question: And at 3.5, 0.815 percent, correct?

21   "Answer: Correct?

22   "Question: And so the 3.4.25 degree sample

23   started with more than twice the amount of impurities as the

24   3.5 sample, correct?

25   "Answer: Mathematically, yes.

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1   "Question: And at four weeks, the 3.5 sample

2   hadn't even reached the starting impurities for the 3.4

3   sample, correct?

4   "Answer: At 3.4 weeks at 25 C, it is

5   2.03 percent. And at pH 3.5, it is 1.23 percent.

6   "Question: Right. And so it's the difference

7   in the starting point of impurities that accounts for the

8   break between the data in the total impurities at 25 degree

9   C between 3.4 and 3.5 pH, correct?

10   "Answer: It may be possible that that could be

11   the difference.

12   "Question: At one point I tried to write this

13   down. I think you said you know we have data supporting at

14   least 18 months shelf life at room temperature and you don't

15   know whether the data was actually filed with the FDA.

16   "Is that -- are my notes accurate as to what you

17   testified?

18   "Answer: That is correct.

19   "Question. What are you referring to when you

20   say you know there's data supporting at least 18 months

21   shelf life at room temperature?

22   "Answer: While I was at Par Pharmaceutical, we

23   were continuing the room temperature stability studies and

24   established data that supports a shelf life of at least

25   18 months.

1   "Question: And was that an improvement over the

2 original Vasopressin, originally approved Vasopressin

3 formulation?

4   "Answer: That is, in my opinion, is an

5 improvement over the original formulation that was initially

6 approved with 12 months -- 12 months of shelf life. This is

7 a significant improvement."

8   (End of videotaped deposition.)

9   MR. KWON: Your Honor, pursuant to the

10 deposition designations, defendants would like to move to

11 admit Exhibits DTX-36, DTX-666, DTX-67, DTX-328, PTX-329,

12 PTX-330, PTX-373, PTX-376 and PTX-377.

13   MR. RHOAD: No objection.

14   THE COURT: No objection. All right. They're

15 admitted.

16   (DTX-36, DTX-666, DTX-67, DTX-328, PTX-329,

17 PTX-330, PTX-373, PTX-376 and PTX-377 were admitted into

18 evidence.)

19   MR. KWON: Your Honor, the next witness is

20 another deposition clip by Matthew Kenney, who is another

21 named inventor of the three -- another named inventor of the

22 patents-in-suit and the '239 patent.

23   Eagle's time for this clip is five minutes and

24 54 seconds. Par's time is four minutes and four seconds for

25 the total time of nine minutes and 58 seconds.

1   Par has also designated counter-designations

2   from Matthew Kenney's June 2020 deposition in the Amneal

3   case. Matthew Kenney was also deposed in his personal

4   capacity, and in that clip Par's time is four minutes and

5   58 seconds and Eagle has no time, so for the total time of

6   four minutes and 58 seconds.

7   MR. RHOAD: Your Honor, just one thing. I'm

8   told that the exhibit we wanted introduced from Dr. Kannan's

9   testimony was not stated on the record, so it's PTX-372 that

10   we would ask be admitted.

11   MR. KWON: No objection, Your Honor.

12   THE COURT: All right. It's admitted.

13   (PTX-372 was admitted into evidence.)

14   (The videotaped deposition of Matt Kenney was

15   played as follows.)

16   "Question: Could you please state your full

17   name for the record.

18   "Answer: Matthew Walter Kenney.

19   "Question: Where do currently work?

20   "Answer: Par Pharmaceutical.

21   "Question: The court reporter has handed you

22   what's been marked as Exhibit 4. The beginning Bates number

23   for this document is Par-VASO_001573. It ends with

24   Par-VASO_0015586.

25   "Okay. Now, this is the original Vasostrict

1   label approved with the approval of the application; is that

2   correct?

3   "Answer: This document says it was from the

4   approval from the -- from 2014 with revised April 2014.

5   "Question: Now that you have reviewed the

6   label, can you please let me know if you worked on or

7   contributed to any portions of this label, including any

8   content thereof?

9   "Answer: I don't recall doing any work that

10   contributed to the information on this label.

11   "Question: Do you recall submitting any

12   information to the regulatory department whatsoever

13   regarding the April 2014 label?

14   "Answer: I don't recall contributing any

15   information for this label.

16   "Question: Now, when you say that pH is most

17   stable at 3.8...

18   "Answer: Mm-hmm, yes.

19   "Question: Is that for all types of Vasopressin

20   formulations?

21   "Answer: I can't say that.

22   "Question: Okay. Is the pH of 3.8 the most

23   stable pH regardless of the type of buffers or components

24   used in Vasopressin formulations?

25   "Answer: Yeah, we can't say that unless we

Kenney - designations

1   studied all buffers.

2   "Question: Okay. Let's talk about reformulated

3   Vasostrict.

4   "Answer: Okay.

5   "Question: Over that product's shelf life, does

6   its pH change?

7   "Answer: There's no trend in pH. There -- it's

8   just some noise.

9   "Question: What do you mean by noise?

10   "Answer: It means just the error in

11   measurement. It might be 3.8 one time, 3.9, 3.7, but it

12   never trends outside that very close buffered range.

13   "Question: Is there a critical difference in

14   stability to Vasopressin formulations between the pH of 3.8

15   and pH of 3.6?

16   "Answer: Critical is subjective. And either

17   way, we would have to do the study with only those two

18   variables changed.

19   "Question: Have you performed such study with

20   regard to the original Vasostrict?

21   "Answer: Original Vasostrict, no, not as far as

22   I recall.

23   "Question: What is different about shelf life

24   between the original Vasostrict and the reformulated

25   Vasostrict?

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1   "Answer: The reformulated Vasostrict has the

2   ability to have a commercially viable room temperature shelf

3   life of 19 months.

4   "Question: Didn't you just testify that the

5   room temperature shelf life of the reformulated Vasostrict

6   is 12 months?

7   "Answer: That's what's stated in the package

8   insert.   It is capable of a 19-month shelf life at room

9   temperature.

10   "Question: Based on Par's internal studies, is

11   that what you are saying?

12   "Answer: Yes.

13   "Question: So in terms of practical

14   consequence, in terms of customer use of the reformulated

15   Vasostrict and the original Vasostrict, both the room

16   temperature and the refrigerated shelf lives are the same;

17   is that right?

18   "Answer: Our reformulated Vasostrict would have

19   less impurities than the original Vasostrict.

20   "Question: At what time point?

21   "Answer: Throughout the shelf life.

22   "Question: Now, you testified earlier that the

23   formulation itself doesn't control the level of impurities

24   at time zero; is that right?

25   "Answer: Correct.

1   "Question: So provided that the measurement of

2   total impurities was undertaken as soon as the drug product

3   gets made, then the level of impurities would not be

4   attributable to the degradation from the drug product; is

5   that right?

6   "Answer: I'm not aware of any impurities that

7   form as soon as you make the drug product.

8   "Question: If the starting impurities in

9   different samples that were tested were different, why would

10   you ever not normalize the data before comparing them?

11   "Answer: And I don't -- I don't know what I

12   would do in that situation. It would depend on how the data

13   looks, if it would make sense to do that, do it that way.

14   "Question: Now, earlier you testified that you

15   believe the pH of 3.8 is the most stable or optimal pH for

16   Vasopressin formulations; is that right?

17   "Answer: Yes.

18   "Question: What does -- in terms of the timing,

19   at what time point are you referring to that pH? So to

20   be -- so are you saying that the pH of 3.8 is the most

21   optimal pH at the time the product is formulated or at some

22   time after?

23   "Answer: According to our studies, pH 3.8

24   affords the most stable drug product over shelf life.

25   "Question: And do you recall reviewing one of

1   the stability tables for the original Vasostrict which

2   started at pH of 3.5 and then 'spiked' to pH 3.8 at 18

3   months?

4   "Answer: Yes. I don't know if 'spiked' is the

5   correct term, but yes, I remember that data table.

6   "Question: So at that pH at 18 months, would

7   that Vasopressin formulation be more stable than when it

8   started out with by the virtue of the pH?

9   "Answer: I don't know. We would have to run

10   that study.

11   "Question: Doesn't studies that Par performed

12   up to this date that show that pH of 3.8 is the best pH,

13   also show that the formulation that increased its pH of --

14   its pH to 3.8 at 18 months would also be most stable?

15   "Answer: No, that cannot be concluded because

16   you are bringing up the original Vasostrict that was a

17   different formulation, it was not buffered and it contained

18   chlorobutanol. So the data we have were on buffered

19   solutions without chlorobutanol, so that batch in particular

20   that you are referencing, that study would have to be

21   carried out to determine if it was more stable than in the

22   other Vasopressin batch.

23   "Question: Okay. Why does the fact that the

24   original Vasostrict has chlorobutanol have any implication

25   on what the most stable pH would be?

1   "Answer: Because when we compare the studies,

2   we have to control the variables, and the studies that I

3   looked at didn't have -- or not all of them had

4   chlorobutanol in them.

5   "Question: So would it be correct to say that

6   the pH of 3.8 is the most stable pH for a Vasopressin

7   formulation that does not contain chlorobutanol and that is

8   buffered?

9   "Answer: According to the studies we've ran,

10   that was our conclusion.

11   "Question: And you cannot extrapolate that

12   conclusion to another Vasopressin formulation at a pH of 3.8

13   that contains chlorobutanol and that is non-buffered; is

14   that right?

15   "Answer: I wouldn't be comfortable making that

16   conclusion based on the non-controlled variables.

17   "Question: But the testing that was done in

18   November 2015 for the pH range of 2.5 to 3.4 used the same

19   lot of Vasopressin as the test that was performed on March

20   17 th, 2015 from the pH range of 3.5 to 4.5; is that

21   correct?

22   "Answer: Yes.

23   "Question: All right. And it's possible that

24   the lot of API would have had more impurities through

25   degradation during the time span starting from March 2015

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1   to the second testing date of November 2015; is that right?

2   "Answer: We would have to compare the stability

3   data on this lot.

4   "Question: So would it be correct to say that

5   every lot of API supplied to Par could have a different

6   level of total impurities?

7   "Answer: If they met -- yes, as long as they

8   were within specification.

9   "Question: Can you quantify how much better 3.8

10   pH is compared to a 3.6 pH?

11   "Answer: So one thing that we can quantify

12   is our current formulation versus the previous Vasostrict,

13   which the previous Vasostrict had an estimated shelf

14   life of 15 months. And then with our formulation work,

15   we were able to improve the estimated shelf life to

16   19 months.

17   "Question: And is that out of refrigeration, in

18   refrigeration, or what?

19   "Answer: That's room temperature stability.

20   "Question: And what is Exhibit 11?

21   "Answer: This is the product development

22   technical report I wrote for Vasostrict 20 units ml pH 3.8

23   acetate buffer, single dose.

24   "Question: In the course of your reformulation

25   work, how many experiments do you think that you ran?

1   "Answer: Probably close to 100.

2   "Question: And in the course of your

3   reformulation work, how many formulations did you and the

4   other inventors of the '785 patent study?

5   "Answer: So it was at least 70 formulations.

6   "Question: Can you please turn to the page

7   ending in 625.

8   "Answer: Okay.

9   "Question: Did you and your -- the other

10   co-inventors of the '785 patent present any conclusion about

11   the most stable region of pH for total impurities within

12   Exhibit 11?

13   "Answer: Yes.

14   "Question. What was that conclusion?

15   "Answer: So the conclusion is based on the data

16   pH 3.8 is the desired target for pH for Vasopressin

17   solutions.

18   "Question: Did you make any conclusions about

19   the most stable region of pH for total impurities within

20   Exhibit 11?

21   "Answer: The most stable region of pH for total

22   impurities is 3.7 to 3.9.

23   "Question: Did you and the other co-inventors

24   of the '785 patent later collect more data for the stability

25   of the reformulated Vasostrict product relative to the

1 original Vasostrict product?

2   "Answer: Yes.

3   "Question: And what did the data show with

4 respect to the relative assay over shelf life?

5   "Answer: So the estimate shelf life of the

6 original Vasostrict was around 15 months. The reformulated

7 Vasostrict with the 3.8 pH acetate buffer, the shelf life

8 was increased to around 19 months.

9   "Question: And similarly, what did the data

10 show with respect to the relative amount of impurities over

11 the shelf life?

12   "Answer: So I don't remember those numbers, but

13 the amount of impurities was decreased dramatically over the

14 estimated shelf life.

15   "Question: And has that been shown -- is the

16 data you're relying on been shown to be statistically

17 significant?

18   "Answer: Yes, so the shelf life calculations

19 are done with FDA compliance software to estimate shelf life

20 with a 95 percent confidence interval.

21   "Question: Just one more question, Mr. Kenney.

22 Even though the labels are the same with respect to storage

23 conditions for the original formulation of Vasostrict and

24 the reformulated product, does Par have data to support a

25 longer shelf life out of refrigeration for the reformulated

1   product?

2   "Answer: Yeah, so our data indicates an

3   estimated shelf life with 95 percent confidence interval of

4   19 months, which means that it is possible to have this

5   product on the market with an 18-month room temperature

6   shelf life on the label."

7   (End of videotaped deposition.)

8   MR. KWON: Your Honor, pursuant to the

9   deposition designations, defendants move to admit DTX-30.

10   MR. GREENE: Your Honor, Blake Greene of

11   Dechert. Plaintiffs move to admit DTX-1115.

12   THE COURT: Will either of you object to the

13   others?

14   MR. GREENE: No objection.

15   MR. KWON: No objection.

16   THE COURT: They're all admitted.

17   (DTX-30 and DTX-1115 were into evidence.)

18   THE COURT: All right. I guess we probably need

19   to give the court reporter a break, so why don't we come

20   back at 3:25. All right? Thank you.

21   (Short recess taken.)

22   - - -

23   (Proceedings resumed after the short recess.)

24   THE COURT: All right. Please be seated. All

25   right. Next?

 1   MR. LASKY: Your Honor, defendants call Dr.

 2   Leonard Chyall.

 3   THE COURT: All right.

 4   ... LEONARD JESSE CHYALL, having been duly

 5   sworn/affirmed as a witness, was examined and testified as

 6   follows...

 7   MR. LASKY: Your Honor, may I approach?

 8   THE COURT: Please.

 9   MR. LASKY: I believe the binders have already

10   been delivered.

11   THE COURT: All right.

12   DIRECT EXAMINATION

13   BY MR. LASKY:

14   Q.   Good afternoon, Dr. Chyall. Can you please introduce

15   yourself to the Court?

16   A.   Good afternoon. I'm Dr. Leonard Chyall.

17   Q.   And did you prepare demonstratives to help with your

18   testimony today?

19   A.   Yes, I did.

20   Q.   Can we look at your slide number 2. Can you please

21   describe your educational background?

22   A.   I received a Bachelor's degree from Oberlin College

23   with a major in chemistry. I then attended graduate school

24   at the University of Minnesota and received a Ph.D. from the

25   chemistry department. I was a post-doctoral fellow at

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1   Purdue University, 1992 to 1996, also in the chemistry

2   department.

3   MR. LASKY: Your Honor, the microphones are very

4   quiet.

5   THE COURT: If the streaming feed is off, does

6   something happen? I think it might be the cooling system.

7   MR. LASKY: Okay. I wasn't myself able to hear

8   Dr. Chyall.

9   THE COURT: You cannot hear him?

10   MR. LASKY: I couldn't hear him very well.

11   THE COURT: I thought you were complaining --

12 not complaining in fairness to you, that there was noise in

13 the air. Try that.

14   THE WITNESS: Can you hear me okay?

15 BY MR. LASKY:

16 Q.   Yes. That's better. Did you write a thesis for your

17 Ph.D.?

18 A.   Yes, I did.

19 Q.   What did the thesis relate to?

20 A.   My thesis concerned the stability of a class of

21 organic compounds called cyclopropanes, so I synthesized

22 those compounds and then conducted a study to measure the

23 study by looking at their degradation products.

24 Q.   Can we move to slide 3, please. Can you describe your

25 profession background for the Court, please.

1   A.   After my postdoctoral fellowship, I worked at Great

2   Lakes Chemical Corporation. That company was in the

3   business of manufacturing and selling organic compounds into

4   a variety of markets and I worked in the R&D division with

5   the focus of identifying new products for the company.

6   In the year 2000, I joined a pharmaceutical

7   services company called SSCI and that company later became

8   Aptuit.

9   SSCI is in the business of helping other drug

10   companies with the chemistry aspect of the drug development

11   concept. So while I was there, I conducted a lot of

12   research that was done on behalf of other drug companies

13   with a focus on the chemistry aspects of their products.

14   And then in the year 2011, I started my own

15   consulting business called Chyall Pharma, where I consult in

16   the same technical areas that I did when I worked at SSCI.

17   Q.   In part of your work experience, have you conducted

18   analytical stability testing of pharmaceutical compositions?

19   A.   Yes. Stability testing is something I've done on

20   numerous occasions, really starting in the year 2000 when I

21   worked at SSCI.

22   Q.   Do you have any teaching experience?

23   A.   Yes, I do. Most recently, I taught introduction to

24   organic chemistry at Purdue University and this was last

25   summer and I taught undergraduates that are majoring in some

1   aspects of the life sciences.

2   Q.   Can you please open your binder to DTX-203-A.

3   A.   Okay. I'm there.

4   Q.   What is DTX-203-A?

5   A.   It's a recent copy of my CV.

6   Q.   Does it accurately represent your education and work

7   experience in the field?

8   A.   Yes.

9   Q.   What types of analyses were you asked to do in this

10   case?

11   A.   I was asked to look at some stability studies that Par

12   scientists conducted that relate to stability of Vasopressin

13   as a function of pH.

14   Q.   And do you have experience relevant to that analysis?

15   A.   Yes. PH dependent stability studies are things that

16   I've done in the past.

17   MR. RHOAD: Your Honor, we tender Dr. Chyall as

18   an expert in the analytical testing and pharmaceutical

19   formulations and evaluation of data for such testing.

20   MR. BLACK: No objection to that extent, but I

21   know that he was not offered as an expert in stability of

22   peptide formulations as the other two experts. His

23   expertise is more limited. Some of the questions may be

24   beyond the scope, but if they are, I will check at that

25   time.

1   THE COURT: All right. Thank you.

2   BY MR. RHOAD:

3   Q.   Dr. Chyall, we move to slide 4. At a high level, what

4   opinions will you be giving the Court today?

5   A.   Today I plan to testify that Par has not shown that

6   the pH limitations of the asserted claims are critical to

7   the Vasopressin stability. Also, I plan to testify that

8   Par's pH study could not have addressed criticality when

9   compared to the April 2014 original Vasostrict label

10   formulation.

11   Q.   What materials did you consider in forming your

12   opinions?

13   A.   I considered the patents-in-suit, the specifications

14   as well as the prosecution histories. I considered earlier

15   Vasopressin patents that are in the same family along with

16   their prosecution history.

17   I considered documents that were produced as

18   part of this litigation from Par's laboratories that

19   involved studies of Vasopressin formulations and I also

20   considered the expert opinions offered by Par's expert, Dr.

21   Kirsch.

22   Q.   Okay. Slide 5.

23   What legal framework did you apply to your

24   criticality analysis in this case?

25   A.   It's my understanding from Eagle's counsel that when a

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1   claimed range overlaps or abuts a range or value in the

2   prior art, then there is a presumption of a prima facie case

3   of obviousness.   The patentee could overcome that

4   obviousness by showing that the claimed range is critical

5   relative to the prior art range or value.

6   But that demonstration of criticality has to be

7   shown across the full scope of the claim, and a difference

8   has to be in difference in kind, not simply a difference in

9   degree.

10   Q.   Okay.   Turning to slide 6, why is criticality

11   important in this case to your understanding?

12   A.   Well, it's my understanding that the original

13   Vasostrict is prior art and that original Vasostrict product

14   has a pH of 3.4 to 3.6 and the pH limitations of the

15   asserted claims concern values that are pH 3.7 to 3.9.

16   Q.   Now, on the left of slide 6, you have DX-30.   What is

17   that document?

18   A.   This is a description from the prescribing information

19   of the original Vasostrict.

20   Q.   Now, you mentioned the abutting range of original

21   Vasostrict and the claims.   What is your understanding of

22   the consequence of that?

23   A.   It's my understanding from the legal framework that,

24   and this is an example of an abutting range, and as a result

25   there's a presumption of obviousness when you have the prior

1   art that abuts those claims.

2   Q.   Okay. Slide 7.

3   Has Par elicited any opinions from its experts

4   in an attempt to show criticality?

5   A.   Yes. I'm aware of opinions offered by Dr. Kirsch in

6   that regard.

7   Q.   And in asserting criticality of the claimed range,

8   what evidence does Dr. Kirsch rely on?

9   A.   Dr. Kirsch relied on experiments done by inventors

10   that could be found in declarations that were put in front

11   of the Patent Office for the prosecution of earlier

12   Vasopressin patents. And those experiments can also be

13   found in examples 9 and 10 of the asserted patents here.

14   Dr. Kirsch is also relying on comparisons of the

15   reformulated Vasostrict product to other Vasopressin

16   products to show criticality.

17   Q.   Okay. Slide 8.

18   Now, let's start with the pH study. Do you have

19   an understanding as to why par submitted the data from the

20   pH study during prosecution of the patent?

21   MR. BLACK: Objection. Lack of foundation.

22   THE COURT: Do you have an understanding? If he

23   doesn't have one, it's not going to go.

24   MR. BLACK: I think he does have one. Okay.

25   THE WITNESS: Yes, I have an understanding.

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1   BY MR. RHOAD:

2   Q.   And where did you get that understanding?

3   A.   From my review of the prosecution history of the

4   earlier Vasopressin patents. In particular, the '478, '239,

5   '526 patents.

6   Q.   And based upon your review of the file histories, what

7   was Par relying on the pH study to show?

8   A.   The pH studies were done to show criticality over

9   another prior art formulation. It's called PPC,

10   Pharmaceutical Partners of Canada, which has a disclosed pH

11   range between 2.5 and 4.5.

12   Q.   And the file histories you were referring to that you

13   had reviewed, what are the exhibit numbers of those?

14   A.   So the 478 patent is DTX-7. The '239 patent is

15   DTX-ten and the '526 patent is JTX-7.

16   Q.   And to be clear, those are the file histories, not the

17   patents themselves; right?

18   A.   That's my understanding.

19   Q.   Now, in your opinion, do the pH studies that Par

20   submitted to the Patent Office in these prosecutions show

21   criticality of the claimed pH range?

22   A.   It's my opinion they do not.

23   Q.   Okay. Moving to slide 9, at a high level, why in your

24   view do the pH studies not show criticality of the claimed

25   range?

Chyall - direct

1   A.   There's two reasons that I have. The first is that

2   the pH study that Par scientists conducted don't address the

3   full scope of the asserted claims and it's also my opinion

4   that those studies themselves, just looking at the data,

5   don't show criticality.

6   Q.   Your first opinion, why is it important that the pH

7   study did not address the full scope of the claims?

8   A.   Because it's my understanding that is a requirement to

9   show criticality in the face of a rejection, an obviousness

10   rejection.

11   Q.   And for purposes of your analysis, what is your

12   understanding of Par's interpretation of the full scope of

13   the pH limitations of the claim?

14   A.   My understanding is Par considers the full scope of

15   the asserted claims to consider Vasopressin formulations

16   that would be manufactured outside of the claimed pH values

17   of 3.7 to 3.9, but then drift into that range at some point

18   during the shelf life.

19   THE COURT: So hold up. The question was

20   actually -- the questioner, Mr. Lasky, referred to the full

21   scope of the pH limitations of the claim. I just want to

22   make sure I'm not missing something as a legal matter

23   because this is new to me.

24   Isn't it the full scope of the claim? In other

25   words, so I'm going to be looking at the pH limitation

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1   relative to the rest of the claim? No?

2   MR. LASKY: That's true, Your Honor, but again

3   the dispute in this case is over the claims, is over the pH

4   limitations in the claim and what those mean and what the --

5   what the -- a difference in pH means with respect to

6   stability and so the point here is that Par is asserting

7   that the claims cover a formulation that is manufactured at

8   3.4 to 3.6 and then drifts into the range for as little, I

9   think we heard, of one minute.

10   THE COURT: I get that, but I just want to make

11   sure, because your question struck me as it was unusual.

12   You've got bullet points in earlier slides and even in the

13   witness' answer to your question, which referred to the full

14   scope of the claim, but your question was about you wanted

15   him to address -- so here's what it says:

16   "Question: Your first opinion, why is it

17   important that the pH study did not address the full scope

18   of the claims?"

19   There was an answer.

20   "Question: And for purposes of your analysis,

21   what is your understanding of Par's interpretations of full

22   scope of the pH limitations of the claim?"

23   MR. LASKY: Correct.

24   THE COURT: That was intentional?

25   MR. LASKY: That was intentional because, of

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1 course, the full scope of the claims is made up of the full

2 scope of each of the individual limitations.

3   THE COURT: Fair enough. I can see how it will

4 be relevant. I want to make sure I understand it.

5   MR. LASKY: Yes. We're going to see -- we're

6 going to talk about a few of those limitations.

7   THE COURT: Thank you.

8 BY MR. LASKY:

9 Q.   So just to reiterate, what is your understanding of

10 Par's interpretation of the full scope of the pH limitations

11 of the claims?

12 A.   My understanding is that Par considers the full scope

13 of the pH limitations to cover products that would be

14 manufactured outside the pH range of 3.7 to 3.9, but then

15 drift into that pH range at some point during its shelf

16 life.

17 Q.   And the pH studies submitted by Par to the -- during

18 prosecution addressed that scenario where the formulation is

19 manufactured outside of the claimed range and then drifts

20 into the claimed range?

21 A.   It's my opinion they do not.

22 Q.   Now, moving to slide 10, here we have some excerpts

23 from the patent-in-suit, JTX-2, at columns 97 to 99 and

24 JTX-3 at column 96 to 98.

25   Now, what are these excerpts?

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1   A.   So these are two examples that are from the patents in

2   suit that describe the pH experiments that were performed by

3   Par's scientists and included in the declaration for the

4   earlier patents. So these experiments describe how samples

5   were prepared and then analyzed.

6   Q.   Now, we see a reference to pH in each of these

7   examples. What do you understand that reference to pH to

8   mean for purposes of these examples?

9   A.   So pH here, the focus is on the initial pH of the

10   various experiments. So what Par scientists did was they

11   prepared a solution of Vasopressin and then adjusted it to a

12   particular pH and then the results obtained were always

13   related back to the initial pH of the experiment.

14   Q.   And is that consistent with your review of the other

15   data that was submitted in the declaration in other

16   prosecution?

17   A.   Yes, it is.

18   Q.   And how does that treatment of pH in examples 9 and 10

19   compare to the full scope of the claim as Par is asserting

20   it in this case?

21   A.   This is much narrower because these experiments don't

22   cover a formulation that would say start out at a lower pH

23   and, for example, drift into a higher pH region, such as the

24   claimed region.

25   Q.   Now, are you aware of any evidence that a Vasopressin

Chyall - direct

1   formulation that is manufactured outside the claimed range

2   but drifts into the claimed range after manufacture confers

3   any stability benefit?

4   A.   I'm not aware of any of that evidence.

5   Q.   Okay. Turning to slide 11, please. What was the

6   composition of the formulation used in the pH --

7   THE COURT: Can I have a sidebar, please?

8   (Sidebar conference held as follows.)

9   THE COURT: I just want to kind of make sure.

10 This is an issue in Markman, was it, when to measure the pH?

11   MR. LASKY: It wasn't an issue with Markman and

12 we're not raising a claim construction dispute, to be clear.

13 We're saying this is how they're interpreting it. We're

14 accepting it for purposes of infringement, accepting it for

15 validity, but their decision to interpret the claims to

16 cover just rising into the claimed claim range for a minute,

17 that has consequences on validity.

18   If they want to show criticality, they have

19 to show it at the full scope of the claims. They have to

20 show --

21   THE COURT: I'm just asking because I have other

22 cases with ranges. So, for instance, in this Markman

23 hearing, nobody asked me to say, to construe -- for

24 instance, you guys didn't ask me to construe the claimed

25 range to be measured at the time of release. That was not

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1   an issue in claim construction?

2   MR. LASKY: That wasn't, and we didn't have the

3   inventor testimony about the, you know, what they actually

4   did at that time, but we didn't, we didn't ask for that.

5   THE COURT: Okay. So you both agree, there was

6   no dispute, nobody asked me to limit the time frame or --

7   MR. BLACK: No.

8   THE COURT: When the range was measured.

9   MR. BLACK: They decided in order to raise

10   that -- you are probably thinking, Your Honor, what they

11   have in the pretrial order by the time they got there, but

12   they had maintained the position without going to Markman

13   the that ordinary meaning was it had to be measured at

14   manufacture. They were going to try to run the case at

15   trial, an ordinary meaning defense on that, which they then

16   dropped.

17   THE COURT: Okay. But then did they raise it?

18   Did it come up in a pretrial order that somebody was

19   suggesting I needed to construe this?

20   MR. LASKY: No.

21   MR. BLACK: I think in the pretrial order you

22   took the position that measurement had to be at manufacture,

23   but they dropped that as we got towards the case.

24   THE COURT: When you say you, you are not

25   referring to me, the Court?

Chyall - direct

1   MR. BLACK: I am sorry, Your Honor.

2   THE COURT: I want to make sure.

3   MR. BLACK: Yes. My recollection is that Eagle

4   was maintaining throughout its expert reports and up to the

5   pretrial order just before trial that the measurement had to

6   be at manufacture.

7   THE COURT: Okay. And, well, it doesn't matter.

8   Now they are not. I just wanted to make sure. I apologize.

9   I think I have another case where that argument is being

10   made. It's when do I measure the pH.

11   MR. BLACK: This argument they are raising now

12   though, I don't know how well developed it is in the

13   pretrial order. We don't think they have the law right. We

14   think they're asking the wrong questions. We'll have to

15   deal with that later.

16   THE COURT: I assume that has to do with, in

17   other words, what does it matter what Par thinks?

18   MR. BLACK: Yes. What's the scope of the claim?

19   THE COURT: That's what you are going to argue?

20   MR. BLACK: Yes. Also, we just saw evidence

21   with Dr. Park that they make their product and then within

22   the first month, the pH rises, so sometimes in the first

23   couple days or weeks. What does any of that mean.

24   THE COURT: Okay.

25   MR. LASKY: Your Honor, we heard from Dr.

1   Kirsch, it can go up one minute until the very end of the

2   shelf life. He already testified that's enough to meet the

3   limitation.

4   THE COURT: I agree, he testified to that.

5   MR. BLACK: It may be a claim construction point

6   that has to be resolved where we can decide the criticality

7   point. That's for post-trial briefing.

8   MS. WU: Your Honor, if I may?

9   THE COURT: Yes.

10   MS. WU: Amneal didn't specifically push this

11 issue because we understood that it was previously vetted in

12 the Eagle case and we didn't want to re-raise things that

13 might have been dealt with, but I do note that claim

14 construction is an issue that would be considered de novo,

15 so a Court can at any time consider that.

16   In one case I had with Judge Robinson, she

17 construed a claim early on in the case and at trial had a

18 different construction because it was new evidence.

19   THE COURT: Okay. But here's the thing. If

20 Amneal is suggesting that -- I'm not saying you are, but if

21 you were going to suggest that post-trial Amneal is going to

22 ask for a new claim construction on validity, it's going to

23 be denied.

24   MS. WU: No. I'm just saying if it's helpful.

25   THE COURT: No. I'm not asking --

1   MS. WU: Amneal would be happy for you to

2   construe it now.

3   THE COURT: I didn't think it would be helpful.

4   MR. BLACK: You're confused because their

5   pretrial order is going in one direction. They never

6   contested --

7   THE COURT: I just wanted to make sure. The

8   line of questioning suggested to me that I might have

9   addressed this in claim construction. We're good.

10   (End of sidebar conference.)

11   THE COURT: All right. Thank you.

12   BY MR. LASKY:

13   Q.   So, Dr. Chyall, before the sidebar we were just

14   discussing again the pH study described in Examples 9 and 10

15   of the asserted patents. What was the composition of the

16   formulations used in those pH studies?

17   A.   The formulations here, the experiments were prepared

18   by dissolving Vasopressin in water along with a ten

19   millimolar acetate buffer and then adjusted the pH.

20   Q.   Now, do the claims of the patents-in-suit require an

21   acetate buffer?

22   A.   No. The claims are broader than that. They would

23   cover an acetate buffer but along the other buffers at other

24   concentrations and then also other excipients and even the

25   absence of buffers and excipients.

Chyall - direct

1   Q.   Are you aware of any data regarding the impact of

2   buffer choice on the stability of a Vasopressin formulation?

3   A.   Yes. I have seen in data from Par scientists.

4   Q.   What data are you aware of?

5   A.   I'm aware of data that was submitted in a declaration

6   that Par provided -- scientists submitted to the Patent

7   Office in support of patentability of another Vasopressin

8   patent.

9   Q.   Okay. Moving to slide 12. Here you have an excerpt

10   from DTX-7, pages 2165 to 66. What is this document?

11   A.   So this is a declaration that Dr. Kannan wrote in

12   support of the patentability of the '478 patent and the data

13   here that I've shown concerns his experiments involving the

14   differences in stability of Vasopressin with an acetate

15   buffer and with a citrate buffer.

16   Q.   You mentioned the '478 patent. How does that relate

17   to the patent-in-suit here?

18   A.   It's an earlier patent in the same family as the

19   asserted patents.

20   Q.   And what did the data that Dr. Kannan submitted in his

21   declaration show?

22   A.   Here, the data showed that the citrate buffer is

23   actually inferior in stabilizing the Vasopressin. The state

24   of the impurities are nearly three times higher, 9.3 percent

25   compared to 2.9 percent for the acetate buffer.

Chyall - direct

1   Q.   Would the asserted claims in this case cover a

2   formulation with a citrate buffer?

3   A.   Yes, it would.

4   Q.   We turn back to examples 9 and 10. And in your

5   opinion, do those pH studies address the full scope of the

6   claims with respect to the composition used?

7   A.   No. The experiment 9 and 10, the studies concern only

8   one buffer and only at one concentration, so it's much

9   narrower.

10   Q.   Okay. Moving to slide 13. So we've discussed your

11   opinion regarding the full scope of the claims. What is the

12   next basis for your opinion on criticality?

13   A.   It's also my opinion looking at the data collected for

14   these pH stability studies, the data itself doesn't show

15   criticality in any event.

16   Q.   Okay. Let's move to slide 14. Here you have some

17   excerpts from DTX-10.2362, pages 2362 to 65. What are those

18   excerpts?

19   A.   These are the charts that Par scientists prepared that

20   show Vasopressin stability as a function of pH and stability

21   is shown in two different ways and at two different

22   temperatures. That's why we have four charts.

23   So the top two are with the impurities that are

24   present after four weeks of storage of these Vasopressin

25   solutions at either 25 or 40 degrees C. And the bottom two

Chyall - direct

1   charts, those concern the amount of Vasopressin that

2   degraded upon storage at either 25 or 40 degrees C for the

3   four-week storage period.

4   And the amount of degradation is expressed as a

5   change in assay.

6   Q.   Let's move to slide 15. Now, on the left of this

7   slide, you have again a page from DTX-10-2362. What is

8   that?

9   A.   So this is the chart that plots the impurities that

10   are in each of these Vasopressin vials at four weeks, so the

11   dots here are the individual data points for the individual

12   pH's and the trend line is just a trend line that goes

13   through the data.

14   Q.   Now, does this graph here show the amount of

15   impurities that were formed over the four-week period of the

16   study?

17   A.   No, no. This is the impurities that are present at

18   week four. And if you look on the chart on the left, excuse

19   me, on the upper right that I prepared, the percent

20   impurities at week four, these values are like 1.23 percent

21   for pH 3.5. It's that week four impurity value,

22   1.23 percent, we would see it there as a 3.5 value.

23   Q.   I was going to ask you about that table next. It's

24   labeled DTX-7, pages 1893 to 96. What is that document?

25   A.   So this is from the Vandse declaration that was

Chyall - direct

1   submitted in support of the '478 patent.

2   Q.   And what are you showing in the table?

3   A.   The table are the impurities that were measured by

4   Par's scientists at the week four period and then also in

5   the center column, those are the initial purities, the week

6   zero impurities that are in the center column.

7   Q.   Now, in your opinion, does this graph show that a pH

8   of 3.7 to 3.9 is critical stability?

9   A.   No, it doesn't. And the blue box, the annotation that

10   I have at the bottom of the chart, this shows a very broad

11   range of stability that starts at around pH 3.5 and extends

12   all the way to pH 4.5.

13   The particular value for the particular

14   impurities present at week four, what I've done in dark blue

15   in my table, I've highlighted values that provide numerical

16   numbers that are just as good, if not better, than the

17   values that were measured for pH 3.7 to 3.9.

18   Q.   Okay. So moving to slide 16, this is another one of

19   those charts from the Kannan declaration.

20   THE COURT: May I just ask a quick question?

21   MR. LASKY: Sure.

22   THE COURT: So the data that is in the table, I

23   just want to make sure, because it looks like it comes from

24   a different document than the graph. But is that data

25   what's represented in the graph?

1   MR. LASKY: Yes. So what they did here --

2   THE COURT: First of all, is it a yes?

3   MR. LASKY: Yes.

4   THE COURT: Okay. Is that going to be an issue?

5   Do you all disagree with that?

6   MR. BLACK: No, Your Honor. The data at DTX-7,

7   which is the file history, this is all data presented to the

8   Examiner.

9   THE COURT: Right. I just want to know because

10   you don't agree. I wanted to see if it's stipulated, but I

11   guess it's not, that this data in the box is reflected in

12   the graph and that it is stipulated to -- let's cut to the

13   chase and just acknowledge it.

14   MR. LASKY: Just to clarify, the graph is only

15   the week four data. We've also included the week 0 data in

16   there. That's not reflected in the graph. So we have a

17   target pH, then there was initial impurities.

18   THE COURT: All right. Zero. But the right

19   column?

20   MR. LASKY: The right column.

21   THE COURT: You're saying the right column, but

22   it's not like he happens to notice there's this similarity.

23   It's the data. I just want to know. Is that in dispute?

24   MR. LASKY: As I understand it, it's not.

25   MR. BLACK: Some of the data --

Chyall - direct

1   THE COURT: Okay.

2   MR. BLACK: -- that's in the patent, the numbers

3   are correct.

4   THE COURT: Okay.

5   MR. BLACK: He read them in. They're a

6   demonstrative, not in evidence.

7   THE COURT: So if I'm looking at it after you

8   guys are gone, I can go, yeah, these numbers are the same

9   numbers that are here. Okay. Thank you.

10   MR. LASKY: Okay.

11   BY MR. LASKY:

12   Q.   Dr. Chyall, to Mr. Black's point, you point to one of

13   the data points that you said is the same as or better than

14   the claimed range in terms of impurities at week four?

15   A.   So if we look at the data point for pH 4.1, the amount

16   of impurities that are present in the vial at week four is

17   .094 percent and that numerical value is actually lower than

18   any of the three values, pH 3.7, 3.8 and 3.9.

19   Q.   Okay. So we were on the second graph, I think. What

20   does the second graph from the Kannan declaration, DTX-10,

21   page 2363, show?

22   A.   This is the same type of impurity data, but now it's

23   for the 40-degree storage condition. So, again, this is a

24   plot of the impurities that are present in each of the vials

25   at week four plotted as a function of pH.

Chyall - direct

1   Q.   And have you done the same thing with the table on the

2   right that you did with the previous impurities chart that

3   we looked at?

4   A.   Yes, I did.   I highlighted the value at pH 4.0 and the

5   reported value for impurities present at week four is

6   1.64 percent and my point is that value at pH 4.0 is

7   actually lower than the value of pH 3.7 that had a reported

8   impurity of 1.75 percent.

9   Q.   So in your view, does this graph show that a pH range

10   of 3.73 to 3.9 is critical to stability?

11   A.   No, it doesn't.   It shows that there's a broad range

12   of stability and adjacent values that are comparable

13   compared to the values that are the same as the claimed

14   range.

15   Q.   Okay.   So let's move to slide 17, please.   And this is

16   the third graph from the Kannan declaration, DTX-10, page

17   2364.   What is that document?

18   A.   So DTX-10 is the declaration that Dr. Kannan submitted

19   to the Patent Office in support of the '239 patent.

20   Q.   Okay.   I apologize.   So what does the graph show?

21   A.   Sorry.   The graph here is a plot of the stability of

22   Vasopressin but now with a focus on the amount of

23   Vasopressin that has degraded.

24   So this is a change in assay as it's called.   So

25   the way this is done is the assay for the value at the week

Chyall - direct

1   zero, the initial assay, that's subtracted from the week

2   four, so you could have an understanding of the change in

3   the assay.

4   Q.   Okay. And so can you explain how the data in your

5   table on the right relates to the data in the chart?

6   A.   So in the appendix of DTX-7, that's the Vandse

7   declaration, it contains the numerical value. What they

8   have in the declaration are the week zero assay and the week

9   four assay, but the chart on the, the column on the right,

10   this is what I did to show what the actual numerical values

11   are that are plotted in the graph that is shown on the left

12   of the slide here.

13   Q.   Now, so just to be clear, what are the dots seen on

14   this graph?

15   A.   The dots are related to the change in assay, so it's

16   the amount of the Vasopressin that's degraded. The higher

17   the data point, that means the more degradation of the

18   Vasopressin that has occurred.

19   Q.   Now, are there dots on this graph for every pH value

20   represented on the graph?

21   A.   No. There's no data point plotted at pH 3.5, 3.7, or

22   3.8.

23   Q.   And have you calculated what the data point should

24   have been at those points?

25   A.   Yes. From the data in the appendix of DTX-7, I

Chyall - direct

1   plotted, well, I calculated that those would actually be

2   negative decreases in assay.

3   Q.   What does it mean to have a negative decrease in

4   assay?

5   A.   Well, that would -- that somehow the Vasopressin is

6   actually improving in purity over time and that is just not

7   scientifically possible, so this just speaks to scatter in

8   the data using this analysis method.

9   Q.   We also see in addition to the dots, there's a wavy

10   line that goes down and then comes up. What is that line?

11   A.   So the straight line is a trend line basically just

12   meant to represent the stability of Vasopressin and the

13   function of pH.

14   Q.   Now, if we focus on the missing point at 3.5, what

15   does the trend line suggest the assay degradation is at that

16   point?

17   A.   So if you look at the pH 3.5 value for the following

18   trend line and then taking it over to the Y axis, the

19   vertical axis, that would suggest around a .9 percent change

20   in assay.

21   Q.   And how does that compare to the actual change in

22   assay for the pH 3.5 study?

23   A.   Well, the pH 3.5 study has effectively no change in

24   assay, so the trend line would suggest greater instability

25   of 3.5 than the actual data shows.

Chyall - direct

1   Q.   Now, how does that compare with where the trend line

2   is for the other two missing data points?

3   A.   So at pH 3.7 and 3.8, those are also values that have

4   a negative decrease, which means that they are stable, an

5   area of stability. Here the trend line actually

6   demonstrates that.

7   Q.   Now, in your opinion, is there any rational scientific

8   basis for leaving out the data points at pH 3.5, 3.7 and

9   3.8?

10 A.   No. It's my opinion that all data points should be

11 plotted on a chart for an experimental study.

12 Q.   So if we consider the data points that are on the

13 graph and the data points that you calculated, does this

14 graph show a pH of 3.7 to 3.9 is critical to stability?

15 A.   No, it doesn't, and for the same reasons, we see

16 adjacent value for assay decrease that are just as good, if

17 not better, than the, for example, the pH 3.9 value.

18 Q.   Can you give us an example of one of those, please?

19   THE COURT: Just hold on a second. So can you

20 clarify again, because the way you're presenting it, it's a

21 table from one document and a graph from the other, and then

22 you are saying, I understand that the witness is saying

23 there was a missing 3.5.

24   Are you saying that some of the data that was in

25 the study that was reflected in the table data was omitted

Chyall - direct

1   from the graph?

2   MR. LASKY: So, Your Honor, what they've done

3   here --

4   THE COURT: And maybe you can ask the witness to

5   elucidate.

6   MR. LASKY: Okay.

7   THE COURT: I've got to say, you know, I'm

8   confused. I'm going to be the fact-finder and it's probably

9   on me. I'm just confused.

10   MR. LASKY: I will ask some further questions.

11   BY MR. LASKY:

12   Q.   So, Dr. Chyall, first of all, where was this graph

13   that you are showing here? How was that provided to the

14   Patent Office?

15   A.   It was provided in a declaration by Dr. Kannan.

16   Q.   And you mentioned that there were some missing data

17   points on the chart. So where did you get the data from

18   that you used to calculate the missing value?

19   A.   So the data points for the week zero and week four,

20   those were included in the appendix of the declaration.

21   Q.   Okay. And so where are you showing your calculation

22   in the table on the right side of this slide?

23   A.   So the calculation that I'm showing, that percent

24   decrease calculation, so the numerical values on the right

25   are the ones that I calculated from the data that was in

Chyall - direct

1   the appendix. And those values correspond to the data

2   points on the chart on the left, but as I testified to

3   earlier, not every data point is actually plotted on the

4   chart.

5   THE COURT: Okay. I'm sorry. I'm going to have

6   to -- so, Doctor, DTX, the table that is on -- we're looking

7   at DDX-4-17, which is a slide.

8   THE WITNESS: Yes, Your Honor.

9   THE COURT: Did you prepare the slide?

10   THE WITNESS: Yes, I did.

11   THE COURT: Okay. And on the slide it appears

12   that there are featured two documents. That's what I'm

13   reading. So the first and the primary one in terms of space

14   is labeled DTX-10.2364.

15   Is that pictorial -- that's a graph?

16   THE WITNESS: Yes, Your Honor.

17   THE COURT: Did you just pull that off of an

18   exhibit or did you modify it?

19   THE WITNESS: I --

20   THE COURT: Or did you do both?

21   THE WITNESS: I did both, Your Honor. The

22   modifications are the blue blocks.

23   THE COURT: Right.

24   THE WITNESS: That has the values that I

25   considered to be comparable and then the pink annotation is

1   the claimed range 3.7 to 3.9 and the bracket is also my

2   notation.

3   THE COURT: All right. Other than the bracket

4   with the annotation that says claimed range, the pink square

5   and the blue box which you added, correct?

6   THE WITNESS: Yes, Your Honor.

7   THE COURT: Is it otherwise, that is a document

8   in evidence. You wouldn't know if it's in evidence, but

9   that's a document that was labeled DTX. Is that right?

10   DTX-10?

11   THE WITNESS: Yes, Your Honor.

12   THE COURT: Okay. Now, the table that's to the

13   right of the slide or on the right side of it, which is

14   identified as DTX-7.1893-96.

15   So there's a document called DTX-7.1893-96.

16   That column that has four columns, is that listed from

17   DTX-7?

18   THE WITNESS: No, Your Honor.

19   THE COURT: Tell me what it is.

20   THE WITNESS: The values for the first three

21   columns --

22   THE COURT: First of all, did you just make up

23   this column or -- the column that has four columns that says

24   target pH, Vasopressin percent assay. The third column says

25   Vasopressin percent assay. The fourth column says decrease.

Chyall - direct

1   Did you create that table?

2   THE WITNESS: I created the table in this

3   format, but the columns -- you'll find in DTX-7, you'll find

4   comparable columns of data. I believe my memory is correct,

5   it's done a little bit differently, where they have all of

6   the week zero data points and then they have another part of

7   the column has the week four data points, so kind of all

8   like in a linear format.

9   What they don't have, Your Honor, is the

10   mathematical calculation in order to get the percent

11   decrease in assay, the fourth column.

12   THE COURT: That column that's percent decrease,

13   that's your work product?

14   THE WITNESS: Yes, Your Honor.

15   THE COURT: And there's no such -- is there a

16   column called percent decrease in the -- in DTX-7, which was

17   submitted to the Patent Office?

18   THE WITNESS: From my memory, there's not, but I

19   need to let you know, Your Honor, that those data points,

20   the actual values, like the .5, .6, .4, those numerical

21   values correspond to locations of the dots on the chart.

22   THE COURT: I got you. I got that much. I'm

23   trying to figure out what's your work product versus what

24   Par submitted to the PTO and that's what is confusing me,

25   see. So it sounds like -- okay. Well, now it disappeared.

Chyall - direct

1   Okay. So this is a slide. The slide wasn't

2   given to the PTO. Right?

3   THE WITNESS: Correct, Your Honor.

4   THE COURT: It sounds like the graph was given

5   to the PTO without the modifications you made. Is that

6   right?

7   THE WITNESS: Yes.

8   THE COURT: And then I guess something else

9   labeled DTX-7, which was a table, was given to the PTO, and

10   you basically created your own table and had taken out data

11   from that table?

12   THE WITNESS: Yes. If you don't mind, there was

13   just briefly on my screen, there was an actual chart of that

14   data that I used to prepare my table.

15   MR. LASKY: James, can you pull that up?

16   This is from DTX-7, which is actually the full

17   file history of the '478. That is from that Vandse

18   declaration that's cited. This is the appendices for those.

19   THE COURT: Okay. So you summarized that or

20   excerpts from it in a chart?

21   THE WITNESS: Yes, Your Honor.

22   THE COURT: Okay. Now, can we go back to the

23   slide? So when you said there was stuff that was missing,

24   there was a 3.5 data point was missing. Is that my

25   recollection?

 1   THE WITNESS: Correct.

 2   THE COURT: Okay. And so was that missing from

 3   the graph in the Kannan declaration? Was it missing from

 4   the table that was in the Vandse declaration or both?

 5   THE WITNESS: The data point is missing from the

 6   graph, and just to remind you, Your Honor, the percent

 7   decrease values are not in the original exhibits, that table

 8   that we had just looked up.

 9   THE COURT: Right.

10   THE WITNESS: So you won't find any of the

11   values on the far right column.

12   THE COURT: I'm good with that. Am I going to

13   be missing any of this other data, like in the red box where

14   you have target pH 3.5, Vasopressin 96.2 for week zero and

15   96.3 for week four, is that in the table that was submitted

16   to the PTO?

17   THE WITNESS: Yes. You'll find the 96.3, 96.2

18   and 96.5. You'll find those values in DTX-7.

19   THE COURT: Okay. Anything other than your

20   notations on the graph in the fourth column that you've

21   added on this slide that was not submitted to the PTO?

22   THE WITNESS: No.

23   THE COURT: Okay. Thank you.

24   BY MR. LASKY:

25   Q.   Just to reiterate, considering the data points that

Chyall - direct

1   you testified are missing from this graph, does the graph

2   show that a pH of 3.7 to 3.9 is critical stability?

3   A.   It's my opinion there's no showing of any critical

4   stability between pH 3.7 and 3.9 from the data on this

5   graph.

6   Q.   All right. Can we move to the next slide, slide 18.

7   This is another graph from the DTX-10, page 2

8   '365. What are you showing on this slide?

9   A.   So this is the assay decrease data. It's the same

10   type of data we had on the previous slide, but now this is

11   for stability at 40 degrees storage conditions.

12   Q.   And the table on the right, did you prepare that in

13   the same way we just described you prepared the table for

14   the previous slide?

15   A.   Yes, I did.

16   Q.   And does this graph show that a pH of 3.7 to 3.9 is

17   critical to stability?

18   A.   No, it doesn't. I just want to refer to some adjacent

19   values at pH 3.5 and 3.6. There, the percent decrease

20   values of 2.2 and 2.5 percent, those values are actually

21   lower than some of the values that were measured in the

22   claimed range.

23   Q.   What does it mean to have a lower value there?

24   A.   What it means, it's better, better stability with

25   respect to preventing the degradation of the Vasopressin.

1   Q.   So we just looked at all four of those graphs

2   individually. If you consider them collectively, in your

3   opinion, do they show that a pH of 3.7, 3.9 is critical

4   stability?

5   A.   It's my opinion that when you look at the data as a

6   whole, there's no showing of criticality.

7   Q.   Now, turn to slide 19. What are you showing on this

8   slide?

9   A.   So this chart on the left is the impurity data for the

10   impurities that are present at week four upon storage of

11   25 degrees C and here I have some annotations onto the chart

12   as well.

13   Q.   Can you describe your annotation?

14   A.   So what I've done is indicated with different colors

15   that these two studies are actually done at different times.

16   The charts are presented as one study, but there were

17   actually two separate sets of experiments.

18   One set was done November of 2015 and that's the

19   low pH region, and then the March 2015 study is the high pH

20   region.

21   Q.   And what are you showing in this table on the right?

22   A.   On the right, this is a table where I summarized the

23   data from DTX-7. These are the percent impurities measured

24   at week four and then also the percent impurities measured

25   at week zero.

1   Q.   Okay. Where did you take this data from?

2   A.   This is from the Vandse declaration that was a part of

3   the file history for the '478 patent.

4   Q.   Are these data points that are in those same

5   appendices we just saw a little earlier?

6   A.   Yes.

7   Q.   Now, how do you know that these would -- this data is

8   from two separate studies conducted at different times?

9   A.   I reviewed the laboratory notebooks that Par

10   scientists maintained the documents for these experiments.

11   Q.   Okay. Moving to slide 20. Here you have some

12   excerpts from DTX-82. What is DTX-82?

13   A.   This is Mr. Matthew Kenney's laboratory notebook, a

14   Par scientist and inventor who documented in preparing the

15   Vasopressin samples that were used for the stability study.

16   Q.   At the top you have some excerpts from a particular

17   page of DTX-82, page 39. What are you showing there?

18   A.   Well, here I'm showing the preparation of the high pH

19   studies that were done in March of 2015 and I've highlighted

20   that the solid Vasopressin, the Vasopressin API lot number

21   056 was used, and it has a potency of 480 units per

22   milligram with an expiry of October 21st, 2015.

23   Q.   And when was this initial formulation done?

24   A.   These -- these experiments were set up on March 17th,

25   2015.

1   Q.   Okay. Now, if we move down to the bottom of your

2   slide here, slide 20, we see some excerpts from page 87 of

3   DTX-82.

4   So what formulations does it show the

5   preparation of?

6   A.   So the November 2015 notebook entry here shows the

7   documentation for the low pH formulation, 2.5 to 3.4.

8   Q.   And what was the lot number of the API that was used

9   in that second study?

10   A.   Here, it's lot number 19056, the same lot as the March

11   7th.

12   Q.   Okay. And how does the date that the second study was

13   conducted compare with the original expiration date below,

14   the lot that was used?

15   A.   The second study was done after the original

16   expiration date for the March study.

17   Q.   Now, did Mr. Kenney or -- did Mr. Kenney do anything

18   to account for that?

19   A.   Yes, yes, he did. You can see in the notebooks that

20   now that lot number 19056, it has a different -- a different

21   potency. Now it's listed as 456 units per milligram. And

22   a new expiration date is also assigned, December 31st, 2015.

23   Q.   Now, have you considered what the impact was of having

24   used -- having conducted these two studies at different

25   times?

1   A.   Yes, I have.

2   Q.   We move to slide 21.   What are you showing on this

3   slide?

4   A.   So here I'm showing the amount of the starting

5   impurity on these pH stability experiments.   So these are

6   the impurity levels that were measured just upon

7   formulation, the so-called week zero impurity.   And the

8   graph, the bar chart that I've prepared here shows a marked

9   increase in impurities for the November 2015 study at the

10   low pH region when you compare it to the level of the

11   starting impurity for the March 2015 study.

12   Q.   And is the data you're plotting here shown in the

13   table on the right side of your slide?

14   A.   Yes, it is.

15   Q.   And where -- excuse me.   Go ahead.

16   A.   I was just going to say that the week zero impurity

17   data here, I obtained that from DTX-7, which is one of the

18   Vandse declarations for the '478 patent.

19   Q.   Again, is that the same appendices we looked at a

20   little earlier?

21   A.   Yes, it is.

22   Q.   So what does this bar graph show with respect to the

23   starting impurities for the two studies?

24   A.   Well, here we can clearly see that there's more

25   impurity in the November 2015 study, starting impurity

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1   compared to the March study.

2   Q.   And can the amount of starting impurities that are in

3   a formulation impact the final amount of impurities at four

4   weeks?

5   A.   Absolutely. If you start with a high level of

6   impurities, those impurities are going to get continued

7   through to week four and you wind up measuring those initial

8   impurities along with the impurities that formed over time.

9   Q.   Now, has Dr. Kirsch asserted an alternative

10   explanation to these differences in starting impurities?

11   A.   Yes. Dr. Kirsch has suggested that the higher

12   impurities are due to the instability of Vasopressin just

13   initially immediately upon putting them into that pH

14   environment. And he points to the gradual slight increase

15   in going from pH 3.4 to 2.5 as evidence of that.

16   Q.   Now, do you agree with Dr. Kirsch's conclusion?

17   A.   No, I disagree. You can see there's a very sharp

18   break in the initial impurity, pH 3.4 compared to 3.5 pH and

19   that distinct break in the amount of impurity falls right at

20   the pH level. It divides the two different pH studies.

21   Q.   Now, given these differences in starting impurities,

22   in your opinion was it appropriate to combine the data from

23   the two studies?

24   A.   No, it wasn't. If you are only going to plot like

25   impurities that are present at week four without any

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1   consideration of the week zero impurities, that's an

2   improper way to plot and analyze the data.

3   Q.   And is there anything that the inventors could have

4   done to account for these differences in starting material?

5   A.   Yes. They could have done a process called

6   normalization, which is just to subtract the initial

7   impurities from the final impurities and then they would

8   know how much formed over time and we saw a similar type of

9   analysis for the assay chart that we were looking at

10   earlier.

11   Q.   Okay. Let's move to slide 22. So over here on the

12   left we again see one of the -- the 25-degree impurity data

13   that was in the Kannan declaration. Does that show -- well,

14   what does that show?

15   A.   Well, here what I've shown with my vertical line right

16   at the differences in color, which define the differences in

17   the chronology, in the experiment, I am showing there's a

18   distinct increase in impurity at the pH 3.4 measurement

19   compared to the 3.5 measurement, and this is impurities on

20   storage for the four-week period here.

21   Q.   And what is the extent of that break?

22   A.   It looks like it's on the order of around one percent

23   or so, a little less than one percent.

24   Q.   Okay. And that's one percent of the total impurities

25   at week four?

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1   A.   Correct.

2   Q.   Okay. Now, you've got a different graph shown on the

3   right. First of all, which annotations have you added to

4   that graph just to clear the record?

5   A.   The graph on the left, all of the color annotations

6   are mine, so that would include the shading for the pH

7   ranges in the red box -- I'm sorry, with the red line, the

8   rectangle and the shaded area for the claimed range, and

9   then the annotation about the claimed range below.

10   Q.   Okay. So the document on the right, what are you

11   showing there?

12   A.   This document on the right is actually normalized

13   impurity data. This is a chart that Par has prepared.

14   Q.   Do you know where this normalized graph came from?

15   A.   Yes. The graph, and then setting aside the color

16   annotation, the graph was from an e-mail correspondence

17   between Dr. Kannan and Mr. Kenney.

18   Q.   Can you turn in your binder to DTX-66, please.

19   A.   Okay.

20   Q.   Is DTX-66 a document you considered in providing your

21   opinions in this case?

22   A.   Yes, it is.

23   Q.   And what do you understand DTX-66 to be?

24   A.   This is an e-mail between Dr. Kannan and Mr. Kenney.

25   Q.   And this is actually a document that we saw Dr. Kannan

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1   talk about during his deposition testimony; right?

2   A.   That's correct.

3   Q.   Okay. And what's the date on this e-mail?

4   A.   March 22nd, 2016.

5   Q.   Okay. And you mentioned that the normalized data

6   was -- well, strike that.

7   What does Dr. Kannan say to Mr. Kenney in this

8   e-mail?

9   A.   Here, he asks, please see if these make sense. If

10   yes, we can clean up and send to Gina.

11   Q.   Okay. And were there some attachments to the e-mail?

12   A.   Yes.

13   Q.   And the graph that we saw on your previous slide,

14   DTX-67, was that one of the attachments to the e-mail?

15   A.   Yes. That was Vasopressin rate RF 25 degrees C.

16   Q.   And were you in the courtroom when Dr. Kannan's

17   testimony was played?

18   A.   I was.

19   Q.   Do you understand who Gina is?

20   A.   Yes. My understanding is she's a Par employee that

21   worked in the legal department.

22   Q.   Okay. In your review of the file histories for the

23   patents, have you seen that normalized graph, DTX-67?

24   A.   I'm sorry. I didn't hear your question.

25   Q.   Yes. In your review of the file histories for Par's

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1   patents, have you seen the normalized graph, DTX-67, was

2   never disclosed to the Patent Office?

3   A.   No, it wasn't disclosed.

4   Q.   Okay. If we can go back to the slide.

5   Now, are the two graphs you're showing on your

6   slide 22, are they describing the same study?

7   A.   Yes, they are. Just the data was plotted in a

8   different way. The data on the left was -- data that was

9   not normalized and the data on the right was the normalized

10 impurity data.

11 Q.   And did the normalized and non-normalized data from

12 the study tell the same story about --

13   THE COURT: Was there one study or two studies?

14   MR. LASKY: Well, sorry. Let me clarify the

15 question.

16   THE COURT: I just want to know. I thought it

17 was two studies.

18   MR. LASKY: It's two studies. What I meant was

19 the 25-degree impurity, so I will clarify that in the

20 record.

21 BY MR. LASKY:

22 Q.   Now, the normalized graph on the right, is that

23 showing the data from the same two studies of the

24 normalized -- that the non-normalized -- let me start again.

25   Is the non-normalized data on the right showing

1   the same two studies as the non-normalized data on the left?

2   A.   Correct.

3   Q.   Okay. And is it showing the same temperature?

4   A.   Yes. This is the 25-degree data.

5   Q.   Now, and also, are they both plotting impurities at

6   four weeks?

7   A.   Correct.

8   Q.   Now, the two, the non-normalized table on the left,

9   does it tell the same story about the stability of the a

10   Vasopressin as the normalized graph on the right?

11   A.   No, it doesn't. The normalized data indicate the

12   broader range of stability and that is what I've meant to

13   highlight here with these two blue boxes.

14   You can see on the chart on the right, when you

15   actually account for the initial impurities that are present

16   in these Vasopressin formulations, you can see impurity

17   levels after the storage condition that are in the same

18   range as the values that are between 3.7 and 3.9. So it's

19   just a broader region of stability once normalization is

20   done to -- this is really data processing.

21   Q.   Now, in your opinion, was there a rational scientific

22   basis for the inventors not to submit the normalized

23   impurities data to the Patent Office?

24   A.   No.

25   Q.   And does the normalized impurities graph show that a

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1   pH range of 3.7 to 3.9 is critical to stability?

2   A.   No, it doesn't.

3   Q.   Okay. If we turn to slide 23, here we have an excerpt

4   from DTX-10, page 2370. What is -- sorry. Page 2369 to 70.

5   What is this document?

6   A.   So this is an excerpt from the Kannan declaration that

7   was put in in support of the '239 patent.

8   Q.   And what did Dr. Kannan represent to the Patent

9   Office?

10 A.   Here, I've highlighted in paragraph 32 that he's

11 telling the Patent Examiner that pH was the only variable

12 that was not normalized.

13 Q.   In your review of the file history, did you see an

14 indication as to why Dr. Kannan was telling the Patent

15 Office that pH was the only variable not normalized?

16 A.   Yes, because the Patent Examiner identified that same

17 break in the data that I identified with respect to the

18 impurities at pH 3.4 and 3.5.

19 Q.   And so why was what Dr. Kannan was saying there about

20 the pH being the only variable that was not normalized

21 relevant to that question?

22 A.   Because the Examiner was interested in knowing whether

23 that break was due to the fact that the studies were done at

24 different times, because the Examiner appreciated that there

25 were two different time frames for these studies.

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1   Q.   And based on his representation that pH was the only

2   variable that was not normalized, what did Dr. Kannan tell

3   the Examiner was the reason for that break?

4   A.   He told the Examiner that the differences in

5   impurities were attributable to changes in the pH and he was

6   not aware of any other factors that would account for the

7   differences in the result for each formulation.

8   Q.   And so then what did he conclude in his statement to

9   the Examiner here?

10 A.   So at the end he concludes that the data presented

11 above are attributable to pH and not to the fact that the

12 data were collected on different days.

13 Q.   Now, starting with the first statement that you've

14 underlined here, pH was the only variable -- well, let's

15 back up a step.

16   When you said pH was the only variable that was

17 not normalized, what other variables are described in this

18 paragraph of Dr. Kannan's declaration?

19 A.   The other variables would be the impurities, the

20 differences in assay and Vasopressin remaining.

21 Q.   Now, was it true, was this statement that pH was the

22 only variable that was not normalized true?

23 A.   No. The impurities were not normalized.

24 Q.   And what is the significance again of the impurities

25 not having been normalized?

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1   A.   Because if you don't take into account your starting

2   level of impurities, then your final measured impurities

3   would also include those starting materials.

4   Q.   So what is your conclusion having seen the normalized

5   data regarding whether the results of the data presented

6   were attributable to pH?

7   A.   The results presented were attributable to also the

8   fact that you started with more impurities in certain

9   experiments.

10   Q.   Now, when was Dr. Kannan's declaration signed?

11   A.   On May 22nd, 2017.

12   Q.   And how does that compare with the date of the e-mail

13   we saw where Dr. Kannan was sending the normalized data to

14   Mr. Kenney?

15   A.   It's later.

16   Q.   Now, in order to have generated a normalized

17   impurities graph like DTX-67 from the data that was

18   presented to the Patent Office, what would the Examiner have

19   had to have done?

20   A.   Well, she would have had to wondered whether these

21   things that were represented were accurate and then she

22   would have had to go into the appendix and find the raw data

23   like I did. And then she would have had to do that

24   subtraction of the impurities in order to get the change in

25   impurity. And then she would have had to have taken that

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1   data and then make her own chart of the normalized impurity

2   and then compare that chart to the chart that was provided

3   in a declaration.

4   Q.   Now, if we move to slide 24. Here we see another

5   graph, DDX-79. What is that graph chart?

6   A.   This chart, without my annotations, was also an

7   attachment to the e-mail correspondence from Dr. Kannan to

8   Mr. Kenney. This chart here is the normalized impurity data

9   for 40 degrees C temperature.

10 Q.   Was this chart disclosed to the Patent Office?

11 A.   No, it wasn't.

12 Q.   Now, what is your understanding of how Dr. Kirsch

13 weighs this 40 degrees normalized data compared to the

14 25 degrees normalized data we saw in DTX-67?

15 A.   It's my understanding from Dr. Kirsch's report that he

16 places more emphasis on the 40-degree data because that

17 provides more of a change in assay and impurity.

18 Q.   And do you agree with Dr. Kirsch's prioritization of

19 the 40 degrees in that way?

20 A.   No. It's my opinion that all of the data should be

21 considered and it's not fair to the data to just emphasize

22 one set over another. This is especially true when you

23 consider that Vasopressin formulations are going to be

24 stored at room temperature and below.

25 Q.   Okay. Considering all the data that you've seen from

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1   the pH studies, if your view, does that support criticality

2   of the claimed range?

3   A.   It is my opinion that it does not.

4   Q.   Okay. Let's skip ahead to slide 26. What other data

5   does Dr. Kirsch rely on for criticality?

6   A.   Dr. Kirsch makes comparisons of the reformulated

7   Vasostrict product to other Vasopressin products to show an

8   increase in performance that he says is evident to

9   criticality.

10   Q.   What does Dr. Kirsch compare reformulated Vasostrict

11   to in that analysis?

12   A.   So he compares reformulated Vasostrict to the original

13   Vasostrict product and he also compares the reformulated

14   Vasostrict to Eagle's ANDA product.

15   Q.   And what is reformulated Vasostrict intended to

16   represent in that comparison?

17   A.   An example of the claimed invention.

18   Q.   And what are original Vasostrict and Eagle's products

19   intended to represent in that comparison?

20   A.   So for this comparison, those are examples that are

21   outside of the claimed invention.

22   Q.   Okay. In your opinion, do those comparisons show

23   criticality of the claimed range?

24   A.   In my opinion, they don't.

25   Q.   Okay. Moving to slide 27, this is DTX-111 you are

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1   showing here. What is that document?

2   A.   This is from the prescribing information of the

3   reformulated Vasostrict product.

4   Q.   And what are you showing here in your annotation?

5   A.   Here, I've highlighted that this product is adjusted

6   to a pH of 3.8.

7   Q.   And how does that compare to the full scope of the pH

8   limitations of the claims as Par is interpreting them for

9   infringement?

10   A.   It's narrow for at least a couple of reasons. The

11   first is that the claimed range is 3.7 to 3.9 and then this

12   is just 3.8, so it's just within that, that broader range.

13   Also, this reformulated product is an example of

14   a product that is targeted to, adjusted, I should say, to

15   have a pH of 3.8, which is in the claims. It doesn't

16   concern a product that would have an adjusted pH that's

17   outside of the claimed range and then drift into the claimed

18   range at sometime later on.

19   Q.   Okay. Moving to slide 28. How does the formulation

20   of reformulated Vasostrict compare to the formulation of the

21   original Vasostrict product and the Eagle product that Dr.

22   Kirsch is comparing it to?

23   A.   Well, there are differences in more than just the pH.

24   The reformulated product does not contain any chlorobutanol,

25   but that excipient is present in the original Vasostrict as

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1   well as Eagle's product.

2   The reformulated product has sodium acetate

3   buffers that's added and then that buffer is not included in

4   the original product or Eagle's product.

5   pH adjusting is different. Sodium hydroxide and

6   hydrochloric acid are used for the reformulated product, but

7   pH adjustments for original Vasostrict in Eagle's product

8   involves acetic acid.

9   Q.   And can those differences other than pH have an impact

10   on the stability of the formulation?

11   A.   Yes. Well, here's an example. We have more than one

12   thing going on, so it's not possible to attribute any

13   difference in performance of just pH, because there are

14   other variables in these products.

15   Q.   And were you in the courtroom when Mr. Kenney's

16   deposition testimony was played?

17   A.   Yes, I was.

18   Q.   And did he have any testimony relevant to that point?

19   A.   Yes, he did. His testimony was consistent with the

20   opinion I just offered in that it's not possible to note the

21   decrease in performance is due to one particular thing when

22   there's no one thing that's being changed, such as

23   chlorobutanol.

24   Q.   And we've also heard some testimony about Par having

25   data to support a longer shelf life for reformulated

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1   Vasostrict. Did you hear that testimony?

2   A.   Yes, I did.

3   Q.   I think there was also a suggestion that reformulated

4   Vasostrict might have lower impurities than original

5   Vasostrict. Did you hear that in the testimony?

6   A.   Yes.

7   Q.   Now, first of all -- well, has reformulated Vasostrict

8   been given a longer shelf life than original Vasostrict?

9   A.   It's my opinion, it's my understanding it has not.

10   The shelf lives are the same.

11   Q.   And if we skip ahead to slide 30, have reformulated

12   Vasostrict been given a broader impurity specification than

13   original Vasostrict?

14   A.   No. The release impurities and the shelf life

15   impurities of five percent and 17 percent respectively,

16   those are the same impurities for the original Vasostrict or

17   the reformulated Vasostrict product.

18   Q.   Now, if there is data to support a longer shelf life

19   for reformulated Vasostrict, can we conclude that that is

20   due to the pH of the product?

21   A.   We can't reach that conclusion because there are other

22   differences other than pH.

23   Q.   Now, have you looked at the pH, sorry, yes. Have you

24   looked at the pH specifications for reformulated Vasostrict

25   in forming your opinion?

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1   A.   Yes, I have.

2   Q.   If we move to slide 31. What is the release

3   specification for pH for reformulated Vasostrict?

4   A.   Anywhere between pH 3.6 and 4.0.

5   Q.   And for reformulated Vasostrict, what's the stability

6   specification for pH?

7   A.   It can be anywhere between 2.5 and 4.5.

8   Q.   What is the document you're relying on for that, for

9   those numbers?

10   A.   This is DTX-72. It's the NDA specification for the

11   reformulated Vasostrict product.

12   Q.   So does a batch of reformulated Vasostrict in order to

13   meet the specification need to have a pH in the claimed

14   range on release?

15   A.   No, it doesn't. It can either be above or below the

16   claimed range, as long as it's within 3.6 to 4.0.

17   Q.   Does a batch of reformulated Vasostrict need to have a

18   pH within the claimed range at any time during its shelf

19   life?

20   A.   No, it doesn't. It's really secondary. Anywhere

21   between 2.5 and 4.5.

22   Q.   So how, if at all, does that impact your criticality

23   analysis?

24   A.   My opinion is that there's no showing of criticality

25   when the release spec and stability spec would allow for the

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1   product to be released and have a shelf life that never

2   falls within the claimed pH region.

3   Q.   Now, if we move forward to slide 32, what other

4   opinion will you be providing the Court today?

5   A.   I also plan to testify that Par's pH study could not

6   have addressed criticality when compared to the April 2014

7   Vasostrict label formulation.

8   Q.   And why is that issue significant in this case?

9   A.   Well, once the Vasostrict label was removed from

10   consideration as prior art, then the focus was on

11   criticality with respect to the PPC, the pharmaceutical

12   partners in Canada, prior art product, which had a broad

13   range of 2.5 to 4.5.

14   Q.   Now, during prosecution of which patent was the 2014

15   Vasopressin label disqualified as prior art?

16   A.   I believe it was during the '239 patent.

17   Q.   And how does the '239 patent relate to the

18   patents-in-suit in this case?

19   A.   It's in the same family as the asserted patent.

20   Q.   And if you consider the date when the Examiner

21   withdrew her rejection and disqualified the label as prior

22   art in prosecution of the '239 patent, when would the

23   applications for the patents-in-suit filed relative to that?

24   A.   Later on.

25   Q.   And was the Examiner the same for the asserted patents

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1   as for the '239 patent?

2   A.   Yes.   Christina Bradley.

3   Q.   Okay.   If we move to slide 33.   Was the 2014

4   Vasostrict label ever cited to the -- by the Examiner during

5   prosecution of the asserted patents?

6   A.   It was referenced, but not as a prior art.   It was

7   just referenced as an evidentiary reference.   The Examiner

8   used it to relate the weight of Vasopressin in milligrams to

9   the units of a potency of Vasopressin.

10   Q.   If we skip forward to slide 35 in the interests of

11   time.

12   If the Examiner had considered the 2014

13   Vasostrict label as prior art during prosecution of the

14   asserted patents, in your view, would the stability data

15   that the inventors submitted to be sufficient to address

16   criticality over that label?

17   A.   In my opinion, it could not have been shown to be

18   critical.

19   Q.   And why is that?

20   A.   The original Vasostrict product is FDA approved

21   product with a narrow pH range, known stability, and the

22   last studies that were done for the criticality declarations

23   and then put into the claims of the asserted patents, those

24   were a four-week study that was done over a broad pH range.

25   It wouldn't have the amount of scientific rigor needed to

1   show criticality when you have this FDA approved product

2   with a pH range that's adjacent to the pH ranges that are

3   being claimed.

4   MR. LASKY: Your Honor, I pass the witness. No

5   further questions.

6   THE COURT: All right.

7   CROSS-EXAMINATION

8   BY MR. BLACK:

9   Q.   Dr. Chyall, good afternoon.

10   A.   Good afternoon.

11   Q.   You were here for Dr. Park's testimony? You were here

12   for Dr. Park's testimony, I assume?

13   A.   Yes.

14   Q.   And you heard him describe a person of skill in the

15   art as someone with a background in pharmaceutical

16   formulations with expertise in peptide formulations. Do you

17   recall that?

18   A.   Yes.

19   Q.   You are not actually a POSA, are you?

20   A.   Well, I have some limited experience with peptide

21   stability. I worked on a project when I was at SSCI that

22   involved stability of peptides.

23   Q.   How long ago was that?

24   A.   I think it was in the -- probably around 2010 or so.

25   No. Earlier than that. I think 2005 or 2007 time frame.

Chyall - cross

1   Q.   Right. You knew I was going to ask that question.

2   That's the best peptide experience you could come up with?

3   A.   It is my peptide experience with respect to studying a

4   peptide.

5   Q.   You do have a lot of expertise in testifying in cases

6   and at deposition and hearings; is that correct?

7   A.   I definitely have served as an expert witness before.

8   Q.   Yes. And by before, you mean you testified in, at

9   deposition over 50 times; right?

10 A.   Yes. Not for 50 different matters, but I have sat for

11 a lot of depositions.

12 Q.   And that's what you told us at your deposition in

13 February of 2020. It has been a year-and-a-half. I'm

14 wondering how Covid was for the deposition, virtual

15 deposition business. How many depositions have you taken

16 since our deposition in this case?

17 A.   I believe just one other.

18 Q.   Okay. All right. So the state of the prior art at

19 the time included, as I believe you said that the

20 formulation of the pH for original Vasostrict was well-known

21 as 3.4 to 3.6; correct?

22 A.   Yes. That's the adjusted pH that is on the label that

23 I showed.

24 Q.   Right. And also your opinion is that the pH had been

25 optimized at 3.5 at the time of the priority date of the

Chyall - cross

1   patent; is that correct?

2   A.   Well, my opinion is that there's a broad range of

3   stability and that's shown by the work that Par scientists

4   did and others, other work, but that is a broad range that

5   would include pH 3.5.

6   Q.   You had a section of your report that said that the pH

7   for Vasopressin formulations had already been optimized.

8   Do you recall that?

9   A.   Yes.

10   Q.   All right. And it's your opinion, is it not, that the

11   pH of Vasopressin formulations had already been optimized as

12   of the priority date of the patents-in-suit; correct?

13   A.   Optimized within -- within a range of around 3.5. I

14   think in my report I mentioned that that range is rather

15   broad.

16   Q.   Actually, I think what you said in your report, and

17   you can correct me if you don't recall, is that by Bi and

18   Singh determined the stability of Vasopressin solutions

19   under various pH environment and found favorable stability

20   at a pH of around 3.5. Those were your words.

21   Do you recall that?

22   A.   Yes. Around 3.5 is important.

23   Q.   And when someone says around 3.5 to a scientist in

24   this space, especially in light of Bi and Singh, that might

25   tell somebody 3.4 to 3.6?

Chyall - cross

1   A.   No.   I disagree.   With respect to Bi, my recollection

2   of that study is it was done at rather coarse pH units.   It

3   wasn't done at the tenth of a pH unit that we're seeing, for

4   example, that Par cited.   I think it was 3.5, 3.75, 3.4.

5   Q.   But at a minimum, your opinion was that those of skill

6   in the art believed that the pH had already been optimized

7   on the priority date; is that correct?

8   A.   Optimized within a rather broad range.

9   Q.   You didn't say the words within a rather broad range

10   in your report or deposition, did you?   That's something

11   that you have now added to your testimony today; isn't that

12   correct?

13   A.   I disagree.   In my report I do remember talking about

14   the broad range of stability of Vasopressin.   That's I think

15   consistent with my testimony here.

16   Q.   Let's take a look at your report.   Paragraph 46.   You

17   had a whole section on page 15 titled pH for Vasopressin

18   formulations had already been optimized; correct?

19   A.   Yes.

20   Q.   And then at the top of the page, page 16, you wrote,

21   in earlier studies, Bi and Singh determined the stability of

22   Vasopressin solutions under various pH environments and

23   found favorable stability of Vasopressin at a pH of around

24   3.5; is that correct?

25   A.   Correct.

Chyall - cross

1   Q.   You had some testimony during the case about the

2   normalization of data.

3   Do you recall that?

4   A.   Yes, I do.

5   Q.   And you spoke most of the time during your testimony

6   about the data that is at 25 degrees Centigrade; is that

7   correct?

8   A.   Correct.

9   Q.   Let me just back up a second because the presentation

10   was so long and there are so many things thrown around, I

11   think we maybe need to clarify a few things.

12   So the inventors studied the pH at different

13   levels, determined impurity level and determined the assay,

14   which is the amount of Vasopressin left in the formulation

15   at two different temperatures, 25 degrees Celsius and

16   40 degrees Celsius; is that correct?

17   A.   Correct.

18   Q.   Okay. And how long were those studies?

19   A.   Four weeks.

20   Q.   Four weeks. So the 25 degrees study at four weeks,

21   25 degrees Celsius is roughly room temperature; is that

22   correct?

23   A.   Yes.

24   Q.   And in the room temperature data you don't really see

25   a signal in your view that there's anything really important

Chyall - cross

1   going on with respect to reducing degradation; is that

2   correct?

3   A.   The degradation is occurring, but the amount of

4   degradant is less at 25 degrees C than 40 degrees.

5   Q.   Right. You saw the curve that went kind of like this

6   and it didn't in your view demonstrate criticality of the

7   range; is that correct?

8   A.   Over, over the range above, and depending on whether

9   you look at assay or impurity, but certainly, a range of

10 above around let's say 3.4 or so. Depending on whether it's

11 normalized or not, you could say that it's stable depending

12 on really what data you look at.

13 Q.   Now --

14 A.   Now, at the lower end, pH of 2.5, there's definitely

15 an increase in impurity and a decrease in assay even at room

16 temperature.

17 Q.   I think I'm making your point, that you don't believe

18 that the 25-degree Celsius room temperature data supported

19 the criticality of the claims; correct?

20 A.   That's correct.

21 Q.   Correct. Now, the inventors, and as you know, Dr.

22 Kirsch, believed, and Dr. Kannan testified by deposition

23 that what was important here was the 40-degree data; is that

24 correct?

25 A.   Correct.

Chyall - cross

1   Q.   And the 40-degree data is much more important here

2   because that is roughly 104 degrees, I think? Forty degrees

3   would be 104, I think?

4   A.   Oh, the conversion to Fahrenheit?

5   Q.   Yes. Plus 40 minus ten percent plus 32?

6   A.   Unless you're talking about weather, I just think in

7   Celsius.

8   Q.   Okay.

9   A.   So I'm not sure.

10   Q.   All right. It's over a hundred degrees, and they do

11   that to try to accelerate -- they call that accelerated

12   stability so that they could see more quickly if there's an

13   effect; is that correct?

14   A.   Well, accelerated stability studies will enhance the

15   degradation, but it's important to always to do both at room

16   temperature and accelerated.

17   Q.   Sure. You might not see a signal for a particular

18   thing of interest at room temperature in a short study, but

19   you might see that signal in a 40-degree accelerated study,

20   which we tell you what's likely to happen months and months

21   into the product; isn't that right?

22   A.   Well, we do have evidence with respect to the

23   Vasopressin stability experiments. We do have evidence of

24   degradation at 25 degrees C at the low pH values.

25   Q.   Okay. Sir, you testified at deposition 50 times. You

Chyall - cross

1   know how this, works. My question: Isn't it true that

2   accelerated stability studies are done at 40 degrees Celsius

3   because the higher temperature accelerates the ability to

4   see a signal in the data over room temperature? Isn't that

5   the purpose of those studies?

6   A.   It will accelerate and you will see an enhancement in

7   any degradation but I need to qualify that and say it's

8   always important to relate to room temperature data because

9   there could be a change in mechanism of the degradation

10   pathway, and it's important here because you could have a pH

11   stability experiment that gives you a pH of 3.8 at

12   40 degrees C, but that pH 3.8 may not be optimum at room

13   temperature.

14   Q.   It's important to look at all the data; right?

15   A.   Yes, sir.

16   Q.   And to make a judgment about whether that data

17   supports criticality of the particular pH range; is that

18   correct?

19   A.   I agree.

20   Q.   And when looking at all the data from the standpoint

21   of a POSA in the peptide field, that is a judgment that you

22   never really had to make yourself, is it?

23   A.   Well, I certainly have studied stability of organic

24   compounds and with respect to understanding the mechanisms

25   of degradation, I understand how Vasopressin is falling

Chyall - cross

1 apart, if you will, under these conditions. So I know the

2 significance of the data for this. I feel like I'm

3 qualified to offer the opinions I'm offering here.

4 Q.   You feel comfortable to give opinions about what a

5 POSA would consider valid data, valid conclusion based on

6 general knowledge about pH and pharmaceutical, but even

7 though you are not a POSA yourself. Correct? Is that

8 fair?

9 A.   Well, I disagree with you that I'm not a POSA. I have

10 the relevant experience in studying stability of organic

11 compounds and pharmaceutics.

12 Q.   Would you at least agree that Dr. Kirsch has more

13 experience than you do?

14 A.   Dr. Kirsch has a lot more experience with peptides

15 than I do.

16 Q.   And would you agree that Dr. Park has a lot more

17 experience with peptides than you?

18 A.   Yes.

19 Q.   But Dr. Park didn't testify on this issue, did he?

20 A.   No, he didn't.

21 Q.   Now, there was a lot of data and confusion about the

22 slides that you presented and if we can put up slide 18,

23 please.

24   This is one of the slides you used. This is the

25 assay data for 40 degrees Celsius. I think you spent a few

Chyall - cross

1   seconds on this slide and kind of blew through it.   But what

2   you are trying to show here is the graph and relate the

3   graph to the data that's in the top of the table; is that

4   correct?

5   A.   Correct.

6   Q.   Okay. Now, all the actual values, the pH values, the

7   assay percentage and the other assay percentage, those

8   values, although not the percentage on the far right, all of

9   that data was submitted to the Examiner; right?

10   A.   The first three columns, but not the fourth.

11   Q.   Right. You didn't mean to imply that the Examiner

12   didn't have the actual values that were sent by the

13   patentee; is that correct?

14   A.   Correct. Didn't have the decrease percent value.

15   That's what I calculated, but she had everything else.

16   Q.   Right. But now with the 40 degree C data, you

17   complained that it had not been normalized; correct?

18   A.   The impurity data was not normalized for both 25 and

19   40 degrees C.

20   Q.   Right. And you showed us slide 22, if we can pull

21   that up. And you showed on the left-hand side the 25 C data

22   in original form and normalized form; correct?

23   A.   Correct.

24   Q.   And the 25 C data on the left doesn't show the

25   critical range and the 25 C data on the right doesn't show

Chyall - cross

1   the critical range either; is that correct?

2   A.   I don't follow the question. With respect --

3   Q.   Neither of these slides show critical range of 3.7 to

4   3.9, is that right, or do you disagree? Maybe it does.

5   A.   The critical range -- so what I've put in the pink is

6   relating to the data point for the pH back to the claimed

7   value.

8   Q.   Yes. Well, you put that same box around 3.7 to 3.9;

9   is that right?

10   A.   Yes.

11   Q.   And that is the pH of the patent in this case?

12   A.   Correct.

13   Q.   Do you believe that the data on the left supports a

14   claim for a critical range?

15   A.   So by the data on the left, if you mean the low, lower

16   than 3.7, it's my opinion that the data -- oh, I'm sorry. I

17   think your question is referring to the non -- the plot on

18   the left?

19   Q.   Yes?

20   A.   Yes. It's my opinion here with respect to the high pH

21   value, I think I testified there were values above 3.9. You

22   can see from the chart it's leveling off at this region.

23   Q.   Okay. Do you believe that that data supports

24   criticality or not?

25   A.   It does not support criticality.

Chyall - cross

1   Q.   Do you believe the normalized data on the right

2   supports criticality or not?

3   A.   Even less so, because the range of stability is

4   broader.

5   Q.   Okay. Now, you also did the same thing with the

6   40-degree data, but very curiously, after accusing -- strike

7   that.

8   But very curiously, on slide 25, your counsel

9   skipped over this slide. And to normalize the data on the

10 defendant is the non-normalized data; correct?

11   MR. LASKY: Objection. Mischaracterizes.

12   MR. BLACK: Well, if I'm wrong and I don't

13 understand the slide, that's okay, the witness can tell

14 me.

15 BY MR. BLACK:

16 Q.   Is the data on the left non-normalized data and the

17 data on the right normalized data?

18 A.   Both of these are normalized. The data on the left is

19 a normalized assay.

20 Q.   I see. The data to the right is normalized

21 impurities; right?

22 A.   Correct.

23 Q.   Okay. I was wrong. But the data on the right looks

24 like the values in the critical range are lower than the

25 other values, so normalization would support criticality,

1 wouldn't it?

2 A.   It's my understanding there has to be a difference in

3 kind and performance and what I'm showing here for both

4 charts is that we -- we see if there's any difference of the

5 values outside the claimed range, they're just slightly

6 higher than the values that are in the claimed range, and I

7 think equally as important, more important, some of the

8 measured value at pH 3.5 and 3.6 for the assay, those values

9 are lower than what's in the claimed range. And then on --

10 so that was with respect to assay.

11   With respect to impurities, we see examples of

12 that on the high end of the claimed range.

13 Q.   You gave an opinion about whether something was

14 scientifically reasonable in withholding data.

15   Do you recall that?

16 A.   Yes, I do.

17 Q.   But, of course, there are a lot of reasons why data

18 might not be sent to the Patent Office. Somebody might have

19 a view that doesn't need to be sent to the Patent Office.

20 Somebody could make a mistake. Somebody at the company

21 could forget to send it along. There are a lot of human

22 reasons why someone would not send data, which would explain

23 why you're sending data to the Patent Office; is that

24 correct?

25 A.   With respect to when data is sent, yes, but also I'm

Chyall - cross

1   looking at the declaration and what was said by the inventor

2   in forming my opinion.

3   Q.   I understand that. But you would agree that there's

4   no evidence that the inventors were somehow deliberate in

5   putting the wrong data in front of the Patent Office. You

6   have no evidence for that, do you?

7   A.   I believe the inventors had the normalized data and

8   didn't submit it.

9   Q.   Yes. But you have previously testified that you

10   didn't have any information, any evidence that the inventors

11   had deliberately withheld data; is that correct?

12   A.   Correct.

13   MR. BLACK: I pass the witness.

14   THE COURT: Thank you. Any redirect?

15   MR. LASKY: No redirect, Your Honor.

16   THE COURT: I just have a quick question for

17   you.

18   So when I look at the slides that you said you

19   prepared --

20   THE WITNESS: Yes.

21   THE COURT: -- and I didn't see a slide -- well,

22   first of all, I thought you testified that the Patent

23   Examiner was aware that there was a November and then the

24   March studies.

25   THE WITNESS: Correct.

Chyall - redirect

1   THE COURT: So nobody hid that from the Patent

2   Examiner?

3   THE WITNESS: That's correct.

4   THE COURT: Okay. And so in terms of

5   recognizing that these two studies were conducted at two

6   dates, the Patent Examiner would have been aware of that?

7   THE WITNESS: Yes, she was.

8   THE COURT: Okay. Thank you.

9   MR. LASKY: May I ask a few questions to follow

10   up on that?

11   THE COURT: Yes.

12   BY MR. LASKY:

13   Q.   Although the Examiner was aware that there were two

14   studies conducted -- well, what did the inventors say was

15   the reason for the break when she questioned whether that

16   was due to the fact that there were two studies or something

17   else?

18   A.   The inventor said that the break in the pH 3.4 and 3.5

19   was due to the pH and not due to the different studies.

20   Q.   And what was the representation Dr. Kannan relied upon

21   to represent that?

22   A.   He represented that the only thing that was not

23   normalized was the pH.

24   Q.   And was that statement true?

25   A.   No, it wasn't.

Chyall - redirect

1   Q.   And was it true that the reason for the break was due

2   to pH?

3   A.   No, because there was a huge amount of impurities,

4   initial impurity at the pH 3.4 value that got carried into

5   the result that was --

6   Q.   Were you here for the testimony of Dr. Kannan?

7   A.   Yes, I was.

8   Q.   And what did Dr. Kannan testify during his deposition

9   that the reason for the break was?

10 A.   He testified that the reason for the break was due to

11 the pH.

12 Q.   But in his deposition, what did he testify to?

13 A.   Oh, the impurities. At deposition he testified that

14 the impurities were higher and that could account for the

15 break.

16 Q.   Right. And was that consistent with what he told the

17 Examiner during prosecution?

18 A.   No. He told the Examiner that the break was due to pH

19 only.

20   MR. LASKY: Thank you.

21   THE COURT: All right. Mr. Black, you retread

22 that. If you want another retread opportunity, I will give

23 it to you.

24   MR. BLACK: It's late. Not necessary, Your

25 Honor.

1   THE COURT: All right. Thank you. Thank you

2   very much. You're excused.

3   THE WITNESS: Thank you.

4   (Witness excused.)

5   MS. WACKER: Your Honor, I have a housekeeping

6   matter with respect to Dr. Park. I accidentally said

7   DTX-47. It was supposed to be DTX-45.

8   The parties are getting a list together. If

9   it's okay with Your Honor, we'll submit that tomorrow

10   morning. They just want to get an e-mail so they can verify

11   all of the data.

12   THE COURT: Okay. So then let's just do this

13   since my deputy clerk had to leave. So we can offer for

14   admission tomorrow morning the exhibits for Dr. Park and for

15   Dr. Chyall. All right.

16   Any other housekeeping measures we need to

17   address?

18   MR. BLACK: Time, Your Honor. How much time?

19   THE COURT: I don't have a count right now.

20   MR. BLACK: Okay.

21   THE COURT: Wait. Maybe we do. We have the

22   parties, a total of 153 minutes today and that Eagle used

23   over 291.

24   MR. BLACK: And is that sufficient to tell us

25   where we are? Okay. Great.

1   THE COURT: I mean, frankly, I will say this,

2   and this is not -- I don't mean to impugn Dr. Chyall at all,

3   but I think other than the last two hours, of course, it's

4   tedious to listen to deposition time.

5   I know you have to do it, play depositions, but

6   frankly, I think counsel have been very good about their use

7   of time. I don't think we're going to have a problem.

8   We're going to finish tomorrow. Right?

9   MR. BLACK: We will finish tomorrow.

10   MR. HALES: Yes. We will finish tomorrow. I

11   have a question I guess in relation to our discussion

12   yesterday about whether there are going to be closings.

13   THE COURT: So we're not going to have closings

14   tomorrow.

15   MR. HALES: Okay.

16   THE COURT: We're going to have briefing

17   pursuant to the expedited schedule that I already set, and

18   then what I'm thinking of is bringing you back for an oral

19   argument soon. And we may have -- I mean, you should be

20   prepared to argue your case tomorrow. Well, let me see.

21   What did you begin the day with? I know you all asked my

22   deputy clerk for the time.

23   MR. HALES: Four -- I think I have it, Your

24   Honor, if you want it?

25   THE COURT: Yes. What do you think you have

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 1    left?

 2                 MR. HALES:  So we started with four hours,

 3    21 minutes this morning.

 4                 THE COURT:  Okay.

 5                 MR. HALES:  And then --

 6                 MR. MOORE:  No, no, no.  Yesterday plaintiffs

 7    used four hours and 21 minutes, I believe, and defendant

 8    used three hours and 37 minutes.

 9                 THE COURT:  Okay.

10                 MR. MOORE:  So with the minutes we've gotten

11    today, we need to make the calculation.

12                 THE COURT:  Why don't you do it.  Take your

13    time.

14                 MR. BLACK:  While we're doing that, Your Honor,

15    two other housekeeping things.

16                 Defendants sent in a definition list in a

17    letter.

18                 THE COURT:  Yes.

19                 MR. BLACK:  We were about to send our own in,

20    but the definitions were actually fairly similar, so we're

21    going to adopt most of them, if not all of them, maybe.

22                 THE COURT:  Okay.

23                 MR. BLACK:  We're just going to look at it

24    tonight and send you some comments tomorrow.

25                 THE COURT:  Yes.  I did notice like in the
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 1 middle of the either second or third page there were a bunch

 2 of quotes with no authority cited for where they came. I

 3 think maybe it was compounding.

 4   MR. BLACK: Okay.

 5   THE COURT: I would be interested where that

 6 definition came from. That wasn't you.

 7   MR. BLACK: Okay. So the thought, Your Honor,

 8 is that we maybe have some back and forth tomorrow at the

 9 end, not formal closings, and then we would do briefing and

10 you might bring us back for closing after that?

11   THE COURT: Yes, but I would like to hear the

12 time. Can I get the time?

13   MS. WACKER: The defendants have used

14 508 minutes, I believe, and Par has used 414.

15   THE COURT: What do you all have left?

16   MR. HALES: 92. Right? I think we had -- was

17 it ten or ten-and-a-half. I can't remember. Ten hours.

18   THE COURT: Right.

19   MR. HALES: Ten hours.

20   THE COURT: You have an hour-and-a-half left.

21   MR. HALES: Correct.

22   THE COURT: Something like that. What does

23 plaintiff have left?

24   MR. BLACK: We have three-and-a-half.

25   MR. HALES: No.

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 1                    THE COURT:  Around three.

 2                    MR. BLACK:  Three hours and six minutes.  Three

 3    hours basically, and we have some depositions tomorrow.  So

 4    the order of battle for tomorrow is I believe -- well, your

 5    case.

 6                    MR. HALES:  Yes.  We have a few more deposition

 7    clips to play.  We trimmed some of those last night.  We'll

 8    see if they are really needed or not.

 9                    MR. BLACK:  Amneal.

10                    MR. HALES:  Yes.  I'm just saying, in terms of

11    our case, our witnesses, we would be turning it over to

12    Amneal at that point.

13                    MS. WU:  Your Honor, we have two witnesses, Dr.

14    Winter.  He'll be up tomorrow morning because it's pretty

15    late now in Brussels followed by Dr. Marais.

16                    THE COURT:  And you're going to get all of that

17    done in and hour-and-a-half?

18                    MR. HALES:  Well, it's not going to be easy.

19    We've tried to be very efficient, but it has not been easy.

20                    MS. WU:  Again, as we talked about previously,

21    Dr. Winter's testimony is going to be very discrete issues.

22    One of the more important things he's doing is presenting

23    some testimony to support Dr. Marais's statistical analysis.

24                    THE COURT:  Doctor -- hold on.  I have to go

25    back.  Dr. Marais's statistical analysis.
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1   MS. WU: Dr. Marais is a statistician.

2   THE COURT: He hasn't testified yesterday?

3   MS. WU: No.

4   THE COURT: I'm thinking, I don't remember the

5   statistical analysis. Okay.

6   MS. WU: We're previewing.

7   MR. BLACK: We do have some significant issues

8   with Dr. Winter going beyond the scope. I don't know

9   what they are planning for sure, but many of the exhibits in

10   his binder were not things that were mentioned in his

11   report.

12   THE COURT: All right.

13   MR. BLACK: So hopefully, that will resolve over

14   the evening.

15   MS. WU: I thought we --

16   THE COURT: All right. Well, I guess --

17   MR. BLACK: Not resolved. The document is not

18   referred to in his report. You can assume I'm going to

19   object.

20   THE COURT: Okay. Well, we should finish

21   tomorrow, that's for sure. I guess the only thing I would

22   say to you is, I mean, I encourage you all to think about

23   transition statements, you know.

24   It's hard to follow some of this stuff and

25   what's the relevance of it and you do have to think about

1   how you present stuff to me.

2   That was really confusing, the stuff about

3   slides and the documents and what's in evidence, and then

4   thinking about, so is this inequitable conduct this is

5   about, is it about obviousness, is it about criticality?

6   You know, you expect a lot and that's on me, I guess, the

7   expectations, but I just can't keep up with it all.

8   Just for what it's worth, you ought to think

9   about that. I left on lunch. I'm working on two other

10   cases. I was here writing a Markman opinion before the case

11   started. Then we had an 8:00 o'clock telephone call. It's

12   hard to juggle it all and I might want to think about it.

13   MR. BLACK: Yes.

14   THE COURT: And also think about picking your

15   spots and your arguments, you know. I always say you lose

16   low hanging fruit. You bring low hanging fruit, my

17   attention is already gone.

18   Anyway, a short way of saying, or maybe a long

19   way of saying think about that. Transition statements often

20   help.

21   MR. BLACK: Yes.

22   THE COURT: I'm about to move into this area

23   because it's going to relate to blank, then I'm like, okay,

24   I kind of get it.

25   MR. HALES: Noted. I appreciate it.

1   THE COURT: And so, Mr. Black, one thing I was

2   thinking is, you know, it does help sometimes if you want to

3   make some point tomorrow before you leave when stuff is

4   fresh in my mind, especially since you've got some time.

5   MR. BLACK: Yes.

6   THE COURT: You know --

7   MR. BLACK: I will be happy especially if he

8   doesn't get a response.

9   THE COURT: I try to be fair.

10   MR. BLACK: We'll keep it in mind having a short

11   presentation. As you can see, Your Honor, this case, there

12   are a lot of issues that unusual even for us and we do this

13   all the time and some of the prior art issues and the way

14   the art is being applied, the infringement issue, the FDA

15   complexity.

16   THE COURT: I think the FDA thing is very, very

17   interesting and, you know, and I'm not faulting anybody, but

18   just -- I mean, part of me thinks we really ought to have an

19   FDA person here who would say, this is what happened. I

20   just found quickly online like a two-minute search, FDA

21   guidance about how you define the RLD and it looks like it's

22   kind of complex.

23   There's a reference in one of the legal filings

24   with the ANDA saying I guess there was a citizen's petition

25   to find out whether their withdrawal was for safety or

1   efficacy, and that seems to impact whether something can be

2   deemed an RLD. I have not studied the statute. I don't

3   even know. But I do find that interesting.

4   And then I find them very interested in how

5   Eagle filed -- I mean, frankly, this occurred to me, which

6   is, well, if the ANDA is changed -- sorry, if the NDA is not

7   original, right, it's reformulated, but the original is

8   withdrawn before Eagle files its ANDA, like, why are you

9   filing an ANDA?

10   I mean, part of me says, do you file an -- I

11   mean, in other words, if your claim is you're not -- the RLD

12   is not the reformulated ANDA, then why do you file an ANDA?

13   But I think it's more complicated than that.

14   MR. BLACK: It's a very complicated topic.

15   THE COURT: All right.

16   MR. HALES: It is complicated. I think maybe

17   the simple thing is, and I'm not an expert in this area, but

18   unless there's a safety or efficacy based reason that one of

19   those would be withdrawn, those various labels still exist.

20   THE COURT: I think it's more complicated than

21   that. I think there's something in the statute that there

22   are like maybe four or five paragraphs that say when

23   something is no longer an RLD. I don't know. You all

24   referred to it as the RLD. That seems every case I've read,

25   everything says the RLD, yet it seems like we have two RLDs?

 1   MR. BLACK: We have one RLD with different

 2   versions. It's not different enough to be a separate RLD.

 3   It's different enough, the pH changed.

 4   THE COURT: That's what your side is.

 5   MR. BLACK: Those are facts. The difference

 6   between the two products are facts, but it's still the same

 7   RLD, I think. Anyway, it is what it is.

 8   THE COURT: It is. I'm just saying there's a

 9   lot of complexity.

10   MR. BLACK: Yes.

11   THE COURT: What I find with the lawyers

12   sometimes, a lot of assumptions. I am dealing with an ANDA

13   case where the parties just briefed all of this stuff and

14   nobody thought to kind of talk to me and say, well, whether

15   the pre-AIA or post-AIA and whether you ought to apply

16   Section 120 and it's a different version, and nobody briefed

17   it, nobody thought about it. It was all just kind of

18   treated.

19   And I've got to write the opinion. I want to

20   explain it. If I am going to write something, I want to

21   explain it to somebody who is like me, high school, and when

22   you try to do that, it is really hard when the lawyers

23   haven't jointed the issues. You can only join so many

24   issues.

25   I feel like that was it. I feel like there was

1   a big thing about --

2   MR. BLACK: Yes, I think you're right, Your

3   Honor. We had a an FDA expert in the Amneal case, but they

4   objected. That is water under the bridge. What I was

5   thinking, I was wondering last night actually whether or not

6   we should have had like an FDA tutorial about some of these

7   things where we could have had more back and forth and

8   colloquy, because that's really about what the law is and

9   how things work. The testimony is kind of tedious and

10   awkward.

11   THE COURT: It's not only tedious. Here's what

12   I think. I think both sides, when it suits them, will say

13   here's what the FDA will do. When it doesn't suit them,

14   they'll say I don't know what the FDA does.

15   I'm thinking I bet the FDA would know.

16   Actually, having worked with the FDA as U.S. Attorney and

17   seeing how things work, I'm not sure the FDA would come up

18   with a straight answer. Okay. But anyway, we'll see you

19   all tomorrow.

20   MR. HALES: Very quick question. I just want to

21   understand.

22   Does that mean if I picked up on you, if we have

23   any kind of closing remarks, is that within the time or is

24   that going to happen the on fly?

25   THE COURT: What I would say to you, you should

1   count on closing your case, an hour-and-a-half, without

2   closing arguments and then we'll just see.

3   MR. HALES: Okay.

4   THE COURT: You kind of get what you get. You

5   all got the hours.

6   MR. HALES: I understand that. The last

7   clarification --

8   THE COURT: I would be ready to answer questions

9   if you have the extra time.

10   MR. HALES: Of course. I understand.

11   Just to clarify, I know the Court takes care of

12   this. Are these numbers already that you've given us, they

13   include, like, sometimes you have the sidebars and the like.

14   Is that adjusted?

15   THE COURT: You know what, I don't know.

16   MR. BLACK: There's no appeal from that.

17   THE COURT: I don't think they fully were, which

18   is why I will be a little bit flexible. I do think you've

19   all, you know, done your part.

20   Yes?

21   MS. WU: Your Honor, one more thing, because

22   every minute will be precious tomorrow. We have disclosed

23   the witness order as to plaintiffs, but I'm wondering if we

24   can switch it up and start with Dr. Winter first thing

25   tomorrow morning.

1   I know it's the first time you're hearing this.

2   I'm just springing it on you, but because there's going to

3   be tech setup for Dr. Winter, it might be helpful to have

4   him go first so that tech setup can happen even before you

5   arrive and he's all set. We don't have to transition after

6   the video for Dr. Winter?

7   MR. BLACK: It's your case. If they want to end

8   with the Kannan deposition clip.

9   THE COURT: However you want to do it. I think

10   it makes sense in terms of the tech stuff.

11   MR. BLACK: Yes.

12   THE COURT: Of course, I told you, I don't know

13   exactly when I get out of my meeting. All right.

14   Everybody, thank you very much.

15   (Court recessed at 5:28 p.m.)

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